AN OPEN CLINICAL STUDY ON SIRANGU (SCABIES) IN CHILDREN WITH THE EVALUATION OF SIDDHA DRUGOMA LEGIUM (INTERNAL) & MUSUTTAI ENNAI (EXTERNAL)

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CERTIFICATE

This is to certify that the dissertation entitled "**AN OPEN CLINICAL STUDY ON SIRANGU"** is a bonafide work done by **Dr. M.SUMATHI**, Government Siddha Medical College, Chennai – 600 106 in partial fulfillmentof the University rules and regulations for award of **SIDDHA MARUTHUVA PERARIGNAR** under my guidance and supervision during the academic year 2014 – 2017.

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INTRODUCTION

Siddha system is an unique disciplinary system of medicine which emphasizes good lifestyles to maintain health. This system is identified with Dravidian culture Persons who have accomplished spiritual perfection are called *Siddhars.* They considered philosophy and medicine two sides of the same coin.

Siddhars defined the laws of nature and gifted the world their knowledge about the universe. According to them .The entire universe is composed of two essential entitile***, Andam*** (Material universe) and ***Pindam*** (Human body).

Many have poured their hearts in beautiful lyrics to describe the supernatural forces, various ailments, diagnosis and treatment etc.. One of the greatest of these is the knowledge of cosmos by *Thirumoolar* a great *siddhar*. He writes

“விளக்கினை ஏற்றி வெளியை அறிமின்
விளக்கினின் முன்னே வேதனை மாறும்
விளக்கை விளக்கும் விளக்குடையார்கள்
விளக்கில் விளங்கும் விளக்கவர் தாமே”

திருமந்திரம்.

From the above quotation it is evident that, with the aid of the light called knowledge, One can know about the universe and succeeds in this the grievances of his soul faces would change and helping him to find the real form of knowledge. The karma of his creation should be dismisses.

Great *Siddhar Thirumoolar*

“மறுப்பதுடல் நோய் மருந்தெனலாகும்
மறுப்பதுள நோய் மருந்தெனச் சாலும்
மறுப்பதனி நோய் வாரா திருக்கு
மறுப்பது சாவையு மருந்தென லாமே”

திருமந்திரம்

The cosmos is based on Humoral theory (Thridoshas) which again founded on five vital elements, Panchaboothas viz, *prithvi ,Appu,Theyu,Vali,Veli*.which plays a vital role in the mode of diagnosis ,investigation, treatment and prevention. Even the modern scientists are not able understand the ancient classification of diseases, parameters and mode of treatments it is beyond their knowledge how it works.

"சுக்கிலத்தில் சுரோணிதம் கலக்குமன்று
பூந்திடும் வியாதி மூன்று"

-சித்த மருத்துவாங்க சுருக்கம்

Paediatric diseases are carried from gene.It defines that the paediatric diseases occurs at the time of fertilization to gestational period. Those paediatric diseases where classified in to Agakkarana noigal and Purakkarana noigal.

Scabies is a contagious disease **(S**ARCOPTES SCABEI) this disease is common in children. The symptoms of *Sirangu* are Nocturnal itching, Burrows, Pruritic papules, pustules, Papulovesicule. Seen in web of hand, wrist, axilla, buttocks, genital area are correlated to Scabies in modern medicine.

Scabies affect 300 millions of people worldwide. The highest prevalence rate may be seen in children, 51% of the children aged 3-7 years being infected.

Hence the author has undergone dissertation work about the clinical trail of ***Oma Legium***(internal) and ***Musuttai Ennai***(external) to prove its safety and efficacy against ***sirangu*** in children

AIM AND OBJECTIVE

Aim:

The aim of this study is to evaluate the efficacy of the siddha medicine ***OMA LEGIUM*** (Internal medicine), ***MUSUTTAI ENNAI*** (External medicine) in the treatment of scabies.

Objective:

- To study the safety and efficacy of the trial medicine.
- The main aim of present study on ***SIRANGU*** is to collect and make a detailed study about the ideas mentioned in siddha concept based on literature.
- To study ***SIRANGU*** in various literature in comparison with modern science.
- Collection and detailed study of various siddha and modern literature dealing with aetiology signs, Symptoms, diagnosis, prognosis, complication and treatment of SIRANGU.
- To study the
    - Acute and Sub Acute toxicity
    - Pharmacological steudies
    - Physicochemical analysis of the trial drug
- To have trial on patient with the trial drug ***OMA LEGIUM*** (internal) and ***MUSUTTAI ENNAI*** (external)
- Scabies can be prevented by avoiding direct skin to skin contact with an infected person.
- Good personal hygiene is important to prevent and control scabies.

SIDDHA ASPECTS

DEFINITION:

முதலில் அரிப்புண்டாகி, அவ்விடத்தில் வேர்க்குரு போல் ஒன்று அல்லது பல குருக்கள் தோன்றி அவை சிறிய நீர்க் கொப்புளங்களாக மாறுவதும் சில சமயம் சீழ கொப்புளங்களாக மாறுவதுமான இயல்புடையது.

Itching followed by one or more papules, this became change into vesicles and sometimes pustules.

AETIOLOGY:

According to *Sirappu maruthuvam,*

- Due to excessive heat of the body the blood is infected to produce Sirangu.
- A type of *Kirumi* causes Sirangu.

Due to excess heat of the body, a type of *Kirumi* penetrates the muscle to produce Sirangu and also the excessive heat impure the blood results in pruritis and itching.

CLASSIFICATION:

In Sirappu Maruthuvam there are two types.

1. Siru Sirangu:

The lesions and burrows are small in a nature

2. Perum Sirangu:

The lesions and burrows are large which may be secondary infection. This is also called as Yaanai Sirangu.

Another classification shows four types. The four types are,

1. Adar Sirangu:

Sirangu occurs densely in clusters.

2. Ottu Sirangu:

Sirangu develops by close physical contact.

3. Kilaitha Sirangu:

The lesion develops adjacent to the primary one.

4. Thutta Sirangu:

Patients suffer with Mega Noi and it is very difficult to treat.

According to T.V.Sambasivam Pillai,

Sirangu is classified into 6 types in T.V. Sambasivam Pillai dictionary.

1. Aanai Sirangu	–	Itching with red scaly patches
2. Sori Sirangu	–	Itching with scales
3. Namuttu Sirangu	–	Itching with pustules
4. Thotar Sirangu	–	Confluent itching
5. Perum Sirangu	–	Itching with wide vesiculation
6. Parangi Sirangu	–	Syphilitic itch

According to PulipaniVaidhyam – 500:

Sirangu Classified into two types.

1. Siru Sirangu

2. Perum Sirangu

The verse for this as follows,

‘நேராக பத்தியந்தானிச் சாபத்தியம்
நிச்சயமா யைந்து நாளேழு நாளாம்
சீராக தலைமுழுகி வருவாயாகில்
சிறுசிரங்கு˙ பெருஞ்சிரங்கும் நில்லாதோடும்
பேராக போகருடகடாட˙ சத்தாலே

பேசினேன் புலிப்பாணி பேசினேனே.”

புலிப்பாணி வைத்தியம் - 500

SITES OF OCCURRENCE:

According to Pararasa seharam, the commonly affected areas are Kai, Viral Idukkugal, Puttam, Araiidukkugal, Marmasthanam, Kongai etc.

CLINCIAL FEATURES:

‘சிறுவனுறுங் கைத்தலத்திற் புறங்கைதன்னிற்
சேறுமறை முதலான மறுதானத்தில்
விறுவிறெனச் சொறிந்துதண்ணீர் கட்டிப் பின்பு
மிகுந்த தினவுண்டாக்கும் விளிம்புகிற்றாய்
இறுகுமிடைசிறுகுநூதல் வரைநேர் கொங்கை
யிருவிழியும் பயினமலையி கனுநல்லாய்
கருவுதல் சேருஞ் **சிரங்கின்** குணமிதென்று
கட்டுரைப்பா ˙ மறையுணர்ந்தகாட்சியோ

பரராசசேகரம் (பாலரோகநிதானம்)

Pararasa seharam (Bala Roga Nithanam) describes the clinical features

1. The lesions occur over the webs of fingers, wrist, inguinal region, buttocks etc.
2. There is intense itching.
3. The lesions like vesicles filled with fluid.
4. The lesions may also occur over the waist, breast and near the eyes.

In the text siddha **Sirappu Maruthuvam**, the clinical features of Sirangu are mentioned as,

1. Itching
2. Vesicles
3. Pustules

4. Lesions commonly occur over the webs of fingers, toes, wrist, folds of axillae, penis, buttocks and inner part and thigh.

MUKKUTRA VAERUPADUGAL : (Pathogenesis)

Disease occurs due to the derangement in

- Uyir thathukkal
- Udal thathukkal
- Kala marupadu (seasonal changes)
- Thinai(living lands)
- Udal vanmai.

UYIR THATHUKKAL:

Mukkutra Iyal:

The function of the three Uyir thathus:

a) Aahaayam (space) + Vayu (air) - Vatha

b) Thee (Fire) - Pitha

c) Appu (water) + Prithivi (Earth) - Kabha

The alteration of three thathu in their reaction to extrinsic or intrinsic factors results in disharmony. This altered harmony and balance variation of the three thathus results in disease. Their natural ratio (1 :½:¼) to each other is discerned by the physician at the wrist and each nadi is individually assessed for its strength, speed and regularity.

The following poem describes the origin of three Uyir Thathus

‘இருப்பான நாடி எழுபதோடீரா
யிரமான தேகத்தில் ஏலப் -பெருநாடி
ஒக்கத் தசமத் தொழிலை யூக்க தசவாயுக்கள்
தக்கபடியானதே சார்பு”

‘சாருந் தசநாடி தன்னில் மூலம் மூன்று
பேருமிடமி பிங்கலையும் பின்னலுடன்- மாறும்
உரைக்கவிரற் காற்றொட்டுணர்த்து மேநாசி
வரைச்சுழி யோமையத்தில் வந்து”
‘வந்தகலை மூன்றில் வாய்வாமபானனுடன்
தந்த பிராணன் சமானனும் சந்தமுறக்
கூட்டுறவில் ரேசித்தல் கூறும் வாதம் பித்தம்
நாட்டுங்கபமே யாம் நாடு”

கண்ணுசாமியம்- பக்கம் 36

The three Thathus are manifested at the wrist and are individually and collectively assessed. These three humour are divided in to various types and have their functions specifically.

FUNCTIONS OF VALI:

‘ஒழுங்குடள் தாதேழ்மூச் சோங்கி இயங்க
எழுச்சிபெற எப்பணியும் ஆற்ற - எழுந்கிரிய
வேகம் புலன்களுக்கு மேவச் சுறுசுறுப்பு
வாகளிக்கும் மாந்தர்க்கு வாயு”

-மருத்துவ தனிப்பாடல் பக்கம்12

According to the physiological function, vali is ten types. They are

S. NO	*VATHAM*	GENERAL FEATURES	CHANGES IN *SIRANGU*
1.	Piranan (Uyir Kaal)	Responsible for respiration and it is necessary for proper digestion	Normal
2.	Abanan (Kizhnokkukaal)	Responsible for all downward forces such as voiding of urine, stools, semen, menstrual flow	Due to constipation Abanan was affect.
3.	Viyanan (Paravukaal)	Dwells in the skin and is concerned with the sense of touch , extension and flexion of the parts of the body and distribution, of the nutrients to various parts of the body	Viyanan was affect due to itching, skin colour changes and dryness.

4.	Uthanan (Melnokkukaal)	Responsible for all kinds of upward motion such as nausea, vomiting etc...	Normal
5.	Samanan (Nadukkaal)	Considered essential for proper digestion, assimilation and carries the digested nutrients to each and every organ	Samanan was affect due to derangement of Viyanan and Abanan.
6.	Naagan	Helps in opening &closing of eyelids	Normal
7.	Koorman	Responsible for vision, lacrimation and yawning	Normal
8.	Kirukaran	Induces appetite, salivation, all secretions in the body including nasal secretion and sneezing	Normal
9.	Devathatthan	Induces and stimulates a person to become alert, get anger, to quarrel, to sleep etc.	Devathathan was affect due to itching at night (sleep disturbances)
10.	Dhananjeyan	Resides in the cranium and produces bloating of the body after death. This leaves from the body after 3days of death, forming a way through the skull.	

In Sirangu – Abanan,Viyanan and Samanan will be mainly affected and Devathathan may also be affected.

FUNTIONS OF AZHAL:

‘பசிதாகம் ஓங்கொளிகண் பார்வைபண் டத்து
ருசிதெரி சத்தி வெம்மை வீரம் - உசித
மதிகூர்த்த புத்திவனப் பளித்துக் காக்கும்
அதிகாரி யாங்கா னழல்”

-மருத்துவ தனிப்பாடல் பக்கம்16

Azhal is functionally divided in to five types. They are

S.NO	PITHAM	NORMAL FEATURES	CHANGES IN SIRANGU
1.	Anar Pitham	Peps up the appetite and aids in digestion.	Anar pitham was affect due to loss of appetite
2.	Ranjaga Pitham	Responsible for the colour and contents of blood.	Ranjaga pitham was affect due to pallor
3.	Saathaga Pitham	Controls the whole body and is held responsible for fulfilling a purpose.	Normal
4.	Pirasaga Pitham	Dwells in the skin and concerned with the shine, glow, texture and its complexion	Pirasaga pitham is responsible for complexion of the skin.so it was affected in all cases
5.	Alosaga Pitham	Responsible for the perception of vision.	Normal

In Sirangu- Anar Pitham, Ranjaga pitham and Pirasaga pitham may be affected.

FUNTIONS OF IYAM:

‘திடமீயு மென்பிணைப்புத் திண்மையுற்ற யாப்பும்
அடலேர் வழுவழுப்பும் ஆக்கைக் - கிடர்க்கு
வெருவாப் பொறுமையும் மேலான காப்பாம்
பெருமைத்தா மையமெனப் பேசு’’

-மருத்துவ தனிப்பாடல் பக்கம்20

S.NO	KABHAM	GENERAL FEATURES	CHANGES IN SIRANGU
1.	Avalambagam	Lies in the respiratory organs, exercises authority over other kabam and controls the heart and circulatory system.	Normal
2.	Kilethagam	Found in stomach as its seat, moistens the food, softens and helps to be digested.	Kilethagam was due to loss of appetite

3.	Pothagam	Hold responsible for the sensory perception of taste.	Normal
4.	Tharpagam	Presents in the head and is responsible for the coolness of the eyes, sometimes may be referred to as cerebrospinal fluid	Normal
5.	Santhigam	Necessary for the lubrication and the free movements of joints.	Normal

It is of five types. They are in Sirangu- Kilethagam may be affected.

UDAL KATTUGAL (SEVEN PHYSICAL CONSTITUENTS):

‘இரமிரத் தந்தசை நெய் நிணமென்பு மச்சைவீந்தென்றேழும் முறையே’’
சரதமொடு மெய்மனத்து நிறைவுதரும்உயிருட்டுத்தாங்கி யிருக்கும்
உரமுதவும் மேடுபள்ளம் நிரவும் நெய்ப் பசையூட்டும் ஓங்கி நிறுத்தும்
பரந்தென்பின் துளைகடொறும் நிரம்பிடுங்கள் முளைதோன்றப் பண்ணும்
தெரிவாய்’’

-சித்த மருத்தூவாங்கச் சுருக்கம் -பக்கம் 334

The human body is made of seven basic physical constituents. These constituents should be in harmony and function normally. Any variation in them will lead to their functional deviations.

The Natural characters of the seven physical constituents

S.NO	UDAL KATTUGAL	GENERAL FEATURES	CHANGES IN SIRANGU
1.	Saaram (Digestive essence)	Responsible for the growth& development. It keeps the individual in good temperament and it enriches the blood.	Saram was responsible for colour of the skin.so it was affected.
2.	Senneer (Blood)	Responsible for the colour of blood and for the intellect, nourishment, strength, vigour and valour of the body.	Senneer was affected due to skin colour changes
3.	Oon (Muscle)	Gives lookable contour to the body as needed for the physical activity. It feed the fat next day and gives a sort of plumpness to the body	Oon was affected due to burrows
4.	Kozhuppu (Fat)	Lubricates the organs to facilitate frictionless functions.	Normal
5.	Enbu (Bones)	Supports & protects the vital organs, gives the definite structure of the body and responsible for the posture and movements of the body	Normal
6.	Moolai (Bone marrow)	Nourishes the bone marrow and brain which is the centre that controls other systems of body	Normal
7.	Sukkilam/ Suronitham(Sperm/ ova)	Responsible for reproduction	Normal

KAALA MARUBADUGAL:

PARUVAKALAM (SEASONS):

Siddhars have classified a year into six seasons each constituting two months.There are some disease which are more prevalent during a particular paruvakalam and study of it will be of much useful for diagnosis.

S. NO	***Perum Pozhuthugal***	***Suvai***	***MUKKUTTRA MARUPAADUGAL***
1.	Kaar Kaalam (Aavani&Purattasi) Aug16 to Oct 15	Inippu,Pulippu,Uppu	*VATHAM*-Vettunilai Vazharchi PITHAM-Thanilai Vazharchi.
2.	Koothir Kaalam. (Iypasi &Karthigai) Oct 16 To Dec15	Inippu.Kaippu,Thuvarppu	VATHAM- Thanilai Vazharchi PITHAM-Vettunilai Vazharchi
3.	Munpani Kaalam (Margazhi & Thai) Dec16 To Feb15	Inippu,Pulippu,Uppu	PITHAM- Thanilai Vazharchi
4.	Pinpani Kaalam (Masi & Panguni) Feb16 To Mar15	Inippu.Pulippu,Thuvarppu	KABHAM- Thanilai Vazharchi
5.	Elavenil Kaalam (Chithirai&Vaikaasi) April16 To June15	Kaippu,Karppu,Thuvarppu	KABHAM- Vettunilai Vazharchi
6.	MudhuvenirKalam (Aani& Aadi). June16 To Aug 15	Inippu	VATHAM- Thanilai Vazharchi

THINAI (LAND):

Siddhars classified the lands in to five types. They are

1. Kurunchi - Mountain range
2. Mullai -Pastoral area of the forest
3. Marudham -The fertile river bed
4. Neithal -The coastal region
5. Paalai - Arid desert

- The winter season gives good health to the man, early summer and latter rainy gives moderate health. Whereas early rainy and latter summer are more prone to diseases, that's why Siddhars called it as Aanaga kaalam
- Marudham nilam is the fertile area where no disease occurs

MUKKUTRAM	**PARUVAKALAM(SEASONS)**			**THINAI**
	Thannilai Vazharchi (Accumulation)	Vaetrunilai Vazharchi (Aggravation)	Thannilai adaithal (Alleviation)	
VATHAM	Muthuvenil kaalam	Kaar kalam	Koothir Kalam	Vatham was predominant in neithal nilam.so it may aggravate the skin diseases.
PITHAM	Kaar kaalam	Koothir kaalam	Munpani Kaalam	Pitha disease is more prevalent in **Mullai** land
KAPHAM	Pinpani Kaalam	Elavenil kaalam	Muthuvenil kalam	Kapha disease is more prevalent in **Kurunchi** land

RELATION BETWEEN MUKKUTRAM, KAALANGAL AND UDAL VANMAI (IMMUNITY):

Siddhars classify Udal vanmai as three types. They are

1. Iyarkai vanmai
2. Kala vanmai
3. Seyarkai vanmai

Since Sirangu patients are suffering with principal symptom, we came to understand that it is because of alteration in Vali thathu and Vali should be the primary causative factor (Muthanmai kutram). It can be confirmed by the words of great Siddhar Therayer

PINIYARI MURAIMAI (DIAGNOSIS):

It means the method of diagnosing the disease.

‘மதித்திடற்கருமை வாய்ந்த
மாண்பரிகாரமெல்லாந்
துதித்திட வுணர்ந்தானேனுந்
துகளறப் பணியின்றன்மை
பதித்திட வுணரானாகிற்
பயனுறானாகாலானே
விதித்திடு பிணித்திறத்தை
விளம்புது முதற்கண்மன்னோ”

-சிகிச்சா ரத்தினதீபம்- பக்கம் 3

The above poem describes that diagnosis is very important for the physician to treat the disease.

Four steps are followed in diagnosing the disease. They are,

a. Poriyaal arithal
b. Pulanal therthal
c. Vinaathal
d. Envagai thervu

In detail,

a. Poriyaal arithal:

In this the physician should carefully observe the changes that occur in the five sensory organs (Pori gal) of the patient.

b. Pulanal therthal:

The physician carefully applies his five senses of perception, smell, taste, vision, touch and sound to understand the condition of the patient.

c. Vinaathal:

The physician should interrogate about the patients name, age, occupation, socio economic status, food habits, history of past illness, history of present illness, family history,

ENVAGAI THERVUKAL

‘நா நிறம் மொழி விழி மலமூத்திரம்
நாடி பரிசமிவை மருத்துவராயுதம்”
-நோய்நாடல் நோய் முதனாடல்-253

தொகுகலுற்று அட்டவிதப் பரிட்சை தன்னை
துலக்கமுறும் பண்டிதலே தெளிவதாகப்
பகுக்கரிய நாடியை நீ பிடித்துப் பாரு
பகர்கின்ற வார்த்தை பார் நாவைபாரு
வகுக்கரிய தேகமெனத் தொட்டுப்பாரு
வளமான சரீரத்தின் நிறத்தைப்பாரு
சகிக்கரிய மலத்தைப்பார் சலத்தை பாரு
சார்ந்த விழிதனைப் பார்த்து தெளிவாய் காணே

–கண்ணுசாமி பரம்பரை வைத்தியம்.

Nowadays advanced diagnostic tools have been developed by modern bio-medical scientists. But Siddhars have given eight diagnostic methodological tools. They are called as Envagai thervu.

Since *Sirangu* is due to the derangement of Vatham and pitham, the Neikuri will be Vatha or Pitha neer.

- So Naadi does not play a vital role in the diagnosis of Sirangu in children.
- In *Sirangu* the Sparisam may be affected due to the papules, pustule, itching.

Complications:

The verse is as follows,

‘**சிரங்கின்** மகோதரக் கரப்பான் செயுங் குணந்தான்
றினவடங்கி வீங்கி மல சலமும் வற்றி
உரம்பயிலு முதா முறவுற் முட்டாகி
யுவாதி மிகுந்தரி குரலாய் மிடறும் விக்கி
வரம்பயிறு மூச்சு மிகு சுவாத முண்டாய்
வாயு மிகுந்தூண் மறந்து தாகமிஞ்சி
இரங்குறவே களை சோக மிகுதியுண்டா
யிராக் காலத் ததிகரிக்கு மியம்புங் காலே.”

- பரராச சேகரம்

Pararasa seharam says that Sirangu, if untreated can cause Mahothara karappan. The features are,

- Itching gets reduced.
- Oedema of the body
- Oliguria
- Impaired defecation
- Hoarseness of voice
- Dyspnoea
- Loss of appetite
- Polydypsia
- These symptoms get exaggerated during night.

***NOI KANIPPU VIVAADHAM* (DIFFERENTIAL DIAGNOSIS):**

1. Kalangakapadi
2. Karappan

மருத்துவம் : (Line of Treatment)

In siddha system of medicine, the main aim of the treatment is to cure the disease by removing the root cause. Treatment is not only for perfect healing but also for prevention and rejuvenation.

The entire siddha system of medicine consists of three great subdivisions namely,

1) *Noillaneri* (Preventive) – *Kaappu*

2) *Noineekkuneri* (Curative methods) – *Neekkam*

3) *Uramaakkumurai* (Strengthening methods) - *Niraippu*

Noillaneri is the special approach of the siddha system where regular dietary habit early rising, physical and mental disciplinarians are all emphasized. Prevention can mostly save our body and soul, but modernization results in alteration of good health, leads to disease.

Siddha system is playing major role in treating and preventing many chronic diseases. Likewise, herbal medicines have several phyto chemicals which exert their beneficial effect on Sirangu

The aim of treatment is

- ✶ To bring the *Mukkutram* in equilibrium.
- ✶ To treat the symptoms of the disease by internal medicines, external applications of medicated oil.

A large number of medicines for *Sirangu* are stated in different literatures. Among them, an economically inexpensive and simple medicine

1. ***Oma Legium*** (internal)
2. ***Musuttai ennai*** (external)

Diet:

Avoid the Brinjal, Kaar arisi, maize, pearl millet, kodo millet, fox tail millet, Sesban, Bitter gourd, Pickles, Tamarind.

Prevention:

Exclude people with scabies from childcare, preschool, school until one day after treatment commences.

All skin to skin contact and other people in the same household should be treated at the same time even if no itching or other symptoms are present.By the time scabies is diagnosed in one person, many other people may have been infested.If everyone is not treated at the same time treatment is likely to be unsuccessful.

Underwear,clothing,towels,bed linen and personal effects such as slippers,dressing gowns and knee rugs used by the affected person in the 72 hours prior to treatment should be laundered using a hot wash cycle(hotter then 50◦c) or hot tumble dried to kill the mites.

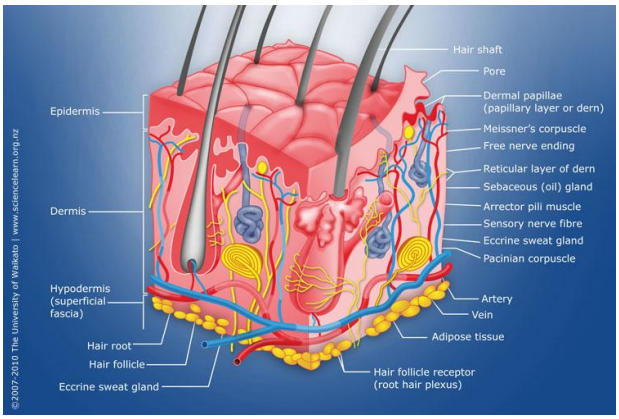
SKIN ANATOMY

The skin is the largest organ of the body. The whole surface of the body is covered by skin. It is a protective, elastic, waterproof and sensitive covering. In a normal person it is about 4kgs of weight and has about 1.75sq meters of surface area. The thickness of the skin varies from 0.5mm to 5mm.

It has two layers,

1, Epidermis

2, dermis



The Epidermis:

The epidermis is nonvascular. It is made up of stratified squamous epithelium. It has 4 layers in all places except palm and sole. In the palm and sole the epidermis has five layers.

Thickness –About 0.1 mm for the ordinary skin . For the palm and sole it is about 0.8-1.4 mm thick.

The layers of the epidermis superficial to deep are,

1 The Stratum Corneum

2 The Stratum Lucidum

3 The Stratum Granulosum

4 The Stratum Germinativum.

The stratum corneum:

It is the Hornified layer containing keratin. It is the husky layer of the epidermis. On the palm and sole it is extremely thick.

The stratum lucidum:

It is transparent in nature. The cells are dying or dead already. It contains a pigment called keratohyalin.

The stratum Granulosum:

It has flattened cells. In the palm and sole it is thick. In other places it is thin. It contains the precursors of keratin.

The stratum germinativum:

Multiplication of cells of the skin takes place in this layer. This layer contains melanin pigment, which gives colouration for the skin. This layer is anchored to the dermis.

The Dermis (or) Corium:

It contains fibrous and elastic connective tissue. It forms papillae projecting into the overlying epidermis. With in the dermis nerve, blood vessels and lymphatics are situated. Within the dermis fat is stored.

The surface of the dermis is made into small papillae. With in these papillae loops of blood vessels are seen. The dermal papillae contain nervous receptors like Meissner' corpuscles. Nerve endings carrying pain sensation are found plenty in the dermis. The dermis has arteriovenous anastomosis. This anastomosis helps in the regulation of the body temperature. The presence of large number of elastic fibres imparts elasticity to the skin. In old age this elasticity is lost, and elastic fibres are replaced by collagen fibres. This causes wrinkling of the skin.

Within the dermis there are roots of hairs, numerous tubules of glands such as sweat and sebaceous glands are found .The coiled ducts of these glands open on the skin surface .There are two types of sweat glands namely

1. Eccrine glands

2. Apocrine glands

Eccrine Glands:

The eccrine glands are distributed all over the body. They are numerous on the skin of the palm, sole and head. They secrete watery sweat containing substances like lactic acid, urea and sodium chloride.

Apocrine Glands:

The apocrine glands are distributed in the axilla around the nipple and female genitalia. They secrete an odourless secretion. The axillary odour is due to bacterial action on the sweat. These glands are induced by adrenaline.

Sebaceous Glands:

The sebaceous glands are small saccular glands. They are flask shaped and open in to the hair follicle. They are found abundant in the face, scalp, external nose, ear. They are absent in the skin of the palm and sole .These glands secrete a fatty secretion called sebum. The sebum keeps the skin supple. Plain muscle fibres called errectores pilorum, cause expulsion of the sebum in to the hair follicle and then to the skin surface.

Ceruminous glands:

Ceruminous glands are modified apocrine type of sweat glands. They are found in the skin of the external ear. They secrete the ear wax.

Appendages of the skin:

Sweat glands, hair, nails and sebaceous glands are considered as the appendages of the skin. Hair develope from epidermis but penetrates into dermis. Hairs are found all over the body expect on the skin of palm, sole and lips. The part of the hair which is visible is called shaft.

The hair follicle is formed by:

1.Root of the hair

2.Connective tissue covering

3. Epithelial covering derived from strattum germinativum. The hair follicle is dilated to form hair bulbs. The hair bulbs are invaded by vascular knots.

Delicate strands of smooth muscles called erectors pilorum arise in the other part of the dermis and run obliquely to the middle of the hair follicle.These muscle causes erection of the hairs. In man it is responsible for the goose flesh appearance of the skin.

The Nails:

The nails are horny plates firmly adherent to the dermis. The nails are situated in the nail bed. At the nail bed the dermis is arranged as ridges. The nail bed is profusely supplied with nerves and it is highly vascular. The proximal part of the nail is found in a groove skin called the nail groove. It is thinnest in this region. The white part of the proximal portion is the lunule. From the lunule the Nail Grow forwards. The body of the nail is firmly attached to the nail bed. The distal end is the free border. On either side the nail is bounded by a fold of skin called nail fold.

Dermatomes:

The area of the skin supplied by a single spinal nerve is known as a dermatome. The adjacent dermatomes overlap each other. So loss of cutaneous sensation in a nerve injury is less due to overlapping of the dermatomes.

Langer's lines:

Presence of linear grooves and ridges on the skin . Surgical incisions may be performed along these lines,the langers line of cleavage. They tend to run longitudinally on the limbs and circumferentially on the neck and the trunk.

Vessels and Nerves:

- Arteries form a network under the reticular and papillary layers.They send capillary loops in to the papillae
- The veins form a superficial plexus under the papillae and also there are deeper venous plexuses.
- Lymphatics begin as blind vessels or networks in the papillae and area deep to them. They drain in to a plexus at the junction of dermis and subcutaneous tissue.
- Efferent nerves supply the smooth muscles blood vessels, erectors pilorum muscles and sweat glands.

Afferent nerve are connected with lamellar corpuscles, tactile corpuscles and hair follicles. They also form nerve endings in the dermis and epidermis.

SCABIES

Definition:

Scabies is a contagious disease and intensely pruritic skin infection caused by the host specific mite scarcoptes scabiei var hominis. (ectoparasite) an obligate human parasite (scabies means scratch).

History of scabies:

Known in animal as mange, the disease has been described since ancient times. A disease not unlike human scabies was described in the Old Testament and also by Aristotle in the fourth Century, However archaeological evidence and Egyptian hieroglyphics, suggests scabies has been irritating mankind for at least 2,500 years. Known in Europe by either the itch or gale, and common place in areas of filth and poverty, the disease was well-described. Celsus a physician of ancient Rome, coined the term “scabies” to describe this condition (2).”Scabies” is derived from the Latin word for “scratch”(scabere).The mite was described in early scientific treatises in 1100AD,but the connection to human disease was not made until 500 years later.

A physician, Giovan cosimo bonomo, described the mite in fluid expressed from the lesions of infested patients with the aid of microscopy. This description is notable for being one of the first accurate descriptions of parasitic Etiology of disease. Bonomo noted that puncture of the small, itching blisters that had not yet scabbed provided relief for those infected. He discovered a small, barely visible white speak within the blister secretions. Acreature with 6 legs, a sharp head, and “two little horns at the end of a snout” could be visualized. He found that most persons with chronic itch where infected by these undergo sexual creatures must reproduction.

Bonomo also documented that the disease was easily spread, not only through mere contact of an infected person, but because the mites could survive outside human skin, and therefore lie in sheets, clothing and bedding.

TYPES:

1. Human scabies.

2. Animals scabies.

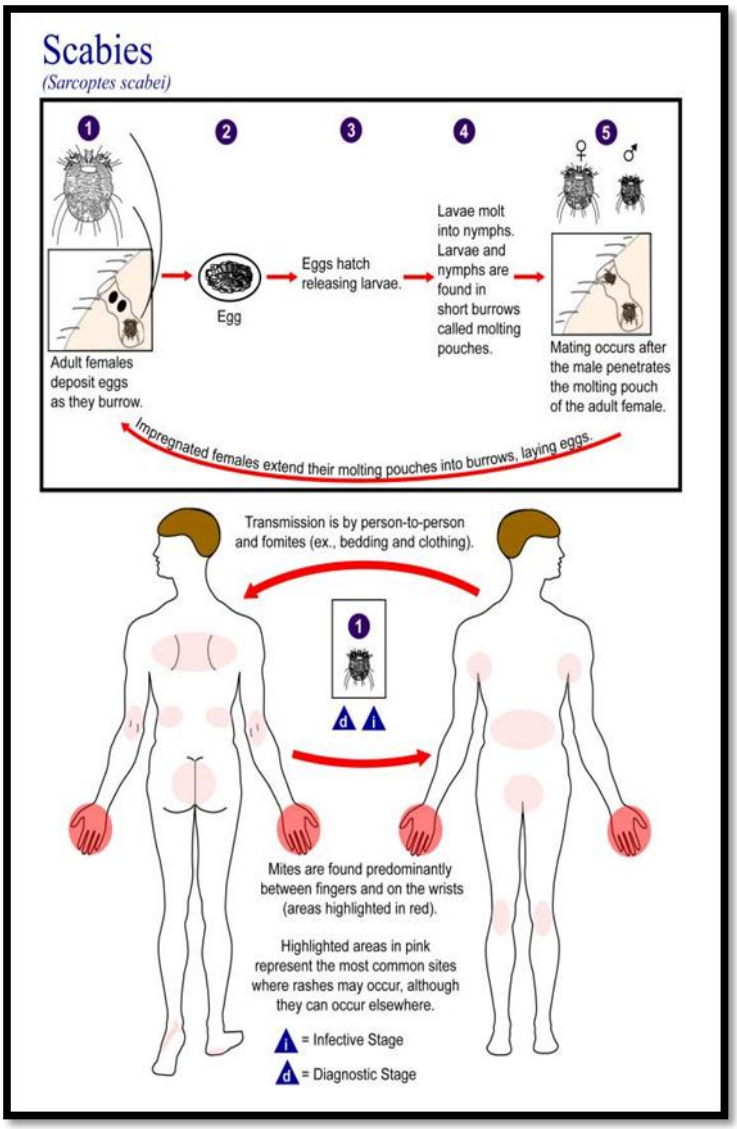
PARASITOLOGY:

- Classification-Sarcoptes scabiei var. hominis
- Phylum-Arthropoda
- Order-Astigmata
- Class-Arachnida
- Subclass-Acari
- Family-Sarcoptidae
- Genus and Species- Sarcoptes scabiei, variation hominis

Life cycle:

Life begins with the eggs being laid in burrows in the upper epidermis, created by a mature female, of the host .The female will lay roughly 2 or 3 eggs per day in the burrow. These eggs will hatch after 3 to 4 days depending on the conditions of the burrow and the host, temperature is a big factor in hatching rate. Eggs are generally between 0.1 and 0.15 mm in length.The next stage is the **larval stage** and these are the form that hatch from the eggs. The Scabies **larvae** immediately begin to dig their own burrows close to the mothers burrow but closer to the skin surface, the larvae do not burrow as deep into the upper epidermis as the mother. The larval burrows are called 'molting pouches' as they stay in their own individual molting pouch until they have molted into the next stage of the life cycle, the nymph stage. This molt into a nymph take about 4 to 5 days.The scabies nymph still stays within the molting pouch, or move to a hair follicle where they undergoes another molting process before the full adult morph is reached. The nymph undergoes one molt to become an adult and this takes roughly 10 days but to become a female adult mite it has to undergo two molts and this takes about 17 days.Once a male adult has fully matured , it looks for a mature female in a molting

pouch and fertilises her and this only occur once in her lifetime, she is then fertile for the whole two months that she will lay eggs for. The life span of the female adult mites is only about 2 months, which is spent laying eggs, the male dies after copulation. The newly impregnated female leaves the molting pouch and searches for an area of skin on the host that is suitable for her to burrow into and lay her eggs. The area may be on the same host or she may be transferred to a new host. Skin that the females prefer are area that have folds or crevices suchas elbows, feet, fingers and genital area. The female than burrows into and horizontally through the upper epidermis to lay her eggs. The life cycle then begins all over again



TRANSMISSION:

Transmission occurs by prolonged close contact with an infected individual, but contact with clothing or bedding that has been infected by an individual.

ETIOLOGY:

Sarcoptes scabiei the itch mites, is the causative organism. It is an oval, ventrally flattened mite. The female mite is 0.3 to 0.5 mm long. It is the fertilized female which burrows into the stratum corneum and there deposites her eggs. A few hours after the start of the burrow, egg laying begins; two or three eggs are laid daily continuously for nearly four to six weeks. The eggs hatch into larvae in three to four days. The larvae are transformed into nymphs, and these in turn into adults.

EPIDEMIOLOGY:

Scabies is usually contracted by close personal contact such as nursing an infested patient, overcrowding, close living quarters as occurs in institutionalized patients, or sleeping together and only infrequently by the common use of contaminated towels, bed linen, and clothing. The female can survive only two or three days away from warm skin. Arlian et al have reviewed the question of infestivity and survival of sarcoptes scabiei in detail, and also the question of cross infestation; they concluded that all varieties of the organism prefer certain hosts but do not insists on them. In a related study they found the mites respond to both host odor and thermal stumuli as a means of host- seeking behaviour.

PATHOGENESIS:

Mellan by points out that sensitization begins about two to four weeks after onset of infection. During this time the parasites may be on the skin and may burrow into it without causing pruritus or discomfort. Severe itching begins with sensitization of the host. In reinfection, itching begins immediately and the reaction may be clinically more intence.

NORWEGIAN SCABIES:

The lesions are so severe that the whole body and limbs including face, scalp and nails may be enveloped in crusts and scales in which large number of parasites are present. It is mainly seen in mental and geriatric patients and persists for years.

ANIMAL SCABIES:

The acarus from cats and gogs rarely attack the human skin, as man is not a suitable host. The affection in such cases is usually transient.

DIFFERENT IAL DIAGNOSIS:

The differential diagnosis depends on the types of lesions present. Burrows are virtually pathognomonic for human scabies. Papulovesicular lesions are confused with papular urticarial, canine scabies, chickenpox, dermatitis herpetiformis. Eczematous lesions may mimic atopic dermatitis, and the less common bullous disordes of childhood may be suspected in the infants with predominantly bullous lesions.

CLINICAL FEATURES:

Itching:

The itching appears a few days after infestation. It may occur within a few hours if the mite is caught a second time. The itch is characteristically more severe at night and affects the trunk and limbs. It does not usually affect the scalp.

Burrows:

Scabies burrows appear as tiny grey irregular tracks between the fingers and on the wrists. They may also be found in armpits, buttocks, on the penis, insteps and backs of the heels. Microscopic examination of the contents of a burrow may reveal mites, eggs or mite feaces (scybala).

Generalized Rash

Scabies rash appears as tiny red intensely itchy bumps on the limbs and trunk. It can easily be confused with dermatitis and hives.The rash of scabies is due to an allergy

to the mites and their products and may take several weeks to develop after initial infestation.

Nodules

Itchy lumps or nodules in the armpits and groins or along the shaft of the penis are very suggestive of scabies. Nodules may persist for several weeks or longer after successful eradication of living mite.

Diagnosis

Scabies can affect children, young adults and the elderly in every community, If you or your child developes a widespread itchy rash, especially if there's been close contact with another itchy person. However, not everyone who itches has scabies; dermatitis is not contagious. If an itchy rash appears the diagnosis can be confirmed by microscopic examination of the contents of a burrow. That dermatologically only recovery of a mite or an egg in about 50% of cases of scabies

INCLUSION CRITERIA:

- Age: 3-7 yrs
- Noctural itching Intense pruritis, particularly at night)
- Burrows
- Papules and papulo vesicles
- Pustules
- Lesions seen in webs of hands, Wrists, Ulnar aspect of forearm, Elbows, Axillae, Feet, buttocks, Palm and Sole, Genital area.
- Patient having any four symptoms are included in my trail.

EXCLUSION CRITERIA:

- Glomerular acute nephritis
- Eczzema
- Photo dermatitis

DIFFERENTIAL DIAGNOSIS:

The differential diagnosis depends on the types of lesions present. Burrows are virtually pathognomonic for human scabies. Papulovesicular lesions are confused with papular urticarial, canine scabies, chickenpox, dermatitis herpetiformis. Eczematous lesions may mimic atopic dermatitis, and the less common bullous disordes of childhood may be suspected in the infants with predominantly bullous lesions.

COMPLICATIONS:

ECZEMATIZATION

It is one of the rare Complication of scabies. Scabetic areas may get sensitized. This sensitization results in Eczematization and well defined circular or oval patch of eczema consisting of erythema, oozing and crusting is formed. If there are severe patches the intervening skin is completely clear.

IMPETIGINIZATION

It is a rare complication of scabies. This is usually due to diminished local resistance. It starts as a superficial bullae containing seropurulent matter the contents coagulate to form a tick stuck on honey coloured crust. Crust is the most important feature of impetiginization. The lesion are usually multiple, the intervening skin is completely normal. Usually there is no pain or itch.

ACUTE GLOMERULONEPHRITIS

Acute glomerulonephritis follows infection by streptococci on the scabetic areas. The onset is usually rapid, with puffiness around the eyes and edema over the feet. Urine colour is characteristically smoky brown, because of formation of acid hematin. The degree of oliguria usually correlates with the severity of the disease. Hypertension is usually present. A typical presentation may also be present which include, convulsions due to hypertensive encephalopathy the urine may grossly normal and edema absent. Left ventricular failure and pulmonary edema due to very high blood pressure, hypovolemia and acute renal failure.

PREPARATION AND PROPERTIES OF TRIAL DRUGS
INTERNAL MEDICINE

OMA LEGIUM:

Ingredients:

Omam **(Tachyspermum ammi)**	**- 3500 grms**
Amukura kizhangu **(withania somnifera)**	**- 35 grms**
Kukil **(shorea robusta))**	**- 35 grms**
Parangi patti **(smilax china))**	**- 35 grms**
Karpoga **arisi (psoralea corlifolia))**	**- 35 grms**
Sugar	**- 350 grms**
Nei **(ghee)**	**- 2lits**

Source of raw drugs:

The required raw drug are procured from a well reputed indigenous drug shop and it will be authenticated by the Pharmacognosist, CRRI Chennai.

Purification of raw drugs:

Raw drugs are purified as mentioned in ***Sikicharathna deepam*** Sarakku Suthi Muraigal.

Preparation:

Take 3500grams of *omam*(Tachyspermum ammi) and add 21.5 lit of water and allow to boil and bring it in 8 part and filter it. Then add 340grms of sugar to it make it as syrup form and add powdered form of *amukura, kukil, parangipattai, karpogaarisi*, each 35grms and ghee 2 lits mix well in order to form a semisolid paste and preserve it in a clean container.

Dose:

5 grms /twice a day (Internal)

Duration: 14-21 days

Ref:Aathmarakshavaitha sarasangiragam –pageno-446, 447

TRAIL DRUG

INTERNAL MEDICINE

Omam(Tachyspermum ammi)

Parangipatti(Smilax China)

Amukkura Kizhangu(Withania Somnifera)

(Karpokaarisi) Psoralea Corylifolia

External Medicine

Kukil(Shorea Robusta)

Musutai(Rivea Ornata)

PROPERTIES OF TRIAL DRUG

1.***Omam***

Botanical Name: Carum copticum

English Name: The bigshops weed

Family: Apiaceae

Suvai: Karppu

Thanmai: Veppam

Pirivu: Karppu

ஓமம்

சீதசுரங் காசஞ் செரியாமந் தம்பொருமல்
பேதியிரைச் சல்கடுப்பு பேராமம்-ஓதிருமல்
பல்லொடுபல் மூலம் பகமிவைநோ யென்செயுமோ?
சொல்லொடுபோம் ஓமமெனச் சொல்.

Chemical Constituent:

α-Pinene, β-Pinene,Carvacrol

Actions:

Stomachic**,** Carminative**,** Antiseptic**,** Stimulant**,** Tonic**,** Sialogogue

Pharmacological activities:

Anti fungal, Anti oxidant,Antibacterial, Antiparasitic

2. ***Paranki pattai:***

Botanical Name: Smilax china

English Name: china root

Family: Liliaceae

Suvai: Inippu

Thanmai: Thatpam

Pirivu: Inippu

பரங்கி பட்டை:

தாகம் பலவாதந் தாதுநட்டம் புண்பிளவை

மேடங் கடிகிரந்தி வீழ்மூலந்- தேகமுடன்

குட்டை பகந்தமேற் கொள்வமனம் போம்பறங்கிப்

பட்டையினை யுச்சரித்துப் பார்.

Chemical Constituent:

Betasitosterol, Beta-daucosterol, 3, 5, 4-trihydroxystibene, Isoengeletin, Engeletin, Kaempferol.

Actions:

Anti-syphilitic, Alterative, Aphordisac, Depurative.

Pharmacological activities:

Anti-inflammatory activity, Anti-psoriaticactivity, Anti-microbial action

3. ***Amukkura- kizhangu***:

Botanical Name: Withania somnifera

English Name: Winter cherry

Family: Solanaceae

Suvai:Kaippu

Thanmai: Veppam

Pirivu: Karppu

அமுக்கிரா கிழங்கு

கொஞ்சந் துவர்ப்பாங் கொடியகயம் சூலையரி

மிஞ்சுகரப் பான்பாண்டு வெப்பதப்பு-விஞ்சி

முசுவுறு தோடமும்போ மோகம்அன லுண்டாம்

அசுவகந் திக்கென் றறி.

Chemical Constituent:

Withanolids –A,Withaferin - A

Action:

Deobstruent, Diuretic,Tonic, Soporific, Sedative

Pharmacological activities:

Anti-stress, Anti-inflammatory activity,Anti-tumour

Antioxidant, Immunomodulatory

4***. Kaarpoga arisi***

Botanical Name: Psoralea corylifolia

English Name: Babchi seeds

Family: Fabaceae

Suvai:Kaippu

Thanmai: Veppam

Pirivu: Karppu

கார்போக அரிசி

கார்போக மாமரிசி கண்டாற் கரப்பான்புண்
பீர்சகுவ நஞ்சிவைபோம் பித்தமுண்டாம்- பார்மீதில்
வாத கபநமைச்சல் வன்சொறிசி ரங்குமறுஞ்
சீத மலர்க்குழலாய் செப்பு.

Chemical Constituent:

Psoralidin, Psoralen, Flavonoids, Neobavaisoflavone,

Isobavachalcone

Actions:

Laxative, Stimulant

Pharmacological activities:

Antiseptic, Anti depressant, Anticancer, Antiinflammatory, Antimicrobial

5***. Kungilium:***

Botanical Name: Shorea robusta

English Name: Sal tree

Family: Dipterocarpaceae

Suvai:Kaippu

Thanmai: Veppam

Pirivu: Karppu

குக்கில்

வெள்ளை யளித்த விரணநா பிக்கமலத்
தொள்ளைவிர ணம்மேகந் தோற்றுகினும்-உள்ளே
வருவரசனைமேற்புண் வரினுஞ் சுவேதச்
சருவரச மேற்பழியைச் சாற்று.

Chemical Constituent:

Non –triterpene, Asiatic acid, Tannic acid,Dipterocarpol

Actions:

Stimulant, Diuretic, Expectorant

Pharmacological activities:

Analgesic activity, Antipyretic activity, Antibacterial, Anti inflammatory, Antiulcer, Immunomodulatory

PREPARATION AND PROPERTIES OF TRIAL DRUGS
EXTERNAL MEDICINE

Musuttai Ennai:

Ingredients:

Musuttai (Rivea ornata)

Source of drugs:

The required drug is procured from a well reputed indigenous drug shop and it will be authenticated by the Pharmacognosist, CRRI Chennai.

Preparation:

Musuttai leaf ground then mixed with gingelly oil.Then boiled gently on fire till it attain.Then filter it stored in air tight container.

Use: External use Only

Ref : Gunapadam -Mooligai Vaguppu pg No:766

PROPERTIES OF TRIAL DRUG

1.***Musuttai*:**

Botanical Name: Rivea ornate,

English Name: Night Glory

Family: Convolvulaceae

Suvai:Kaippu,karppu

Thanmai: Veppam

Pirivu: Karppu

முசுட்டை:

மாதே முசுட்டையது வாதமொடு ஐயத்தைத்
தீதே புரிநீரைத் தீர்க்குங்காண் - வேதனைசெய்
வன்மலத்தைத் தள்ளும் வறட்சி சொறிசிரகைச்
சன்மமறப் போக்கிவிடு சாற்று.

Chemical Constituent:

Non –triterpene, Asiatic acid,Tannic acid,Dipterocarpol

Actions:

Stimulant

Diuretic

Expectorant

Pharmacological activities:

Anti inflammatory

TRIAL DRUGS

INTERNAL MEDICINE:

OMA LEGIUM

EXTERNAL MEDICINE:

MUSUTTAI ENNAI

MATERIALS AND METHODS

CLINICAL STUDIES:

After finishing the toxicity studies 40 paediatric cases were selected on the basis of inclusion criteria from the OPD of *kuzhanthai maruthuvam Department*, Arignar Anna Govt Hospital, Chennai-106 during the period of 2015-2017.

The study was approved by **Institutional Ethics Committee (IEC)** and the approval number is **GSMC-CH-ME-04/21/2015**

STUDY DESIGN & CONDUCT OF THE STUDY:

Study type:

An open clinical study.

Study place:

Arignar Anna Government Hospital of Indian medicine.

Government Siddha Medical College.

Arumbakkam,

Chennai-600 106.

Study duration:

12 months.

Treatment period:

14-21days

Population and sample:

Population consist of paediatric patient attending the OPD of Arignar Anna Govt Hospital, Chennai-106.

The sample consists of patients 3-7 yrs age group fulfilling all the inclusion criteria and exclusion criteria.

Inclusion criteria:

- Age: 3-7 yrs.
- Nocturnal itching.
- Burrow.
- Pruritic Papules.
- Pustules.
- Papulovesicles.

Lesions seen in

- web of hand ,
- wrists,
- ulnar aspect of forearm,
- elbow,
- axillae,
- feet,
- buttock,
- palms and sole
- genital area.

Exclusion Criteria:

- Psoriasis
- Papular utricaria.
- Dermatitis herpetiformis.

Withdrawal Criteria:

- Exacerbations of symptoms.
- Intolerance to the drug and development of adverse reactions during the drug trial.
- Any other acute illness.
  Patients turned unwilling to continue in the course of clinical trial.

Assessments and Investigations

A. Clinical Assessment.

B. Siddha Assessment.

C. Laboratory investigations.

Clinical Assessment

- Nocturnal itching.
- Burrow
- Pruritic papules
- Papulovesicles.
- Pustules.
- Lesion seen in web of hand, wrist, aspect of foreman, elbow, axilla, feet, buttocks,palms and sole.
- Nodular lesions in genital area.

Siddha Assessment

- Naa
- Niram
- Mozhi
- Vizhi

- Sparisam
- Malam
- Naadi
- Moothiram
- Neer kuri, Nei kuri

Laboratory Investigations

Blood:

TC, DC, ESR, Hb.

Urine:

Album, Sugar, Deposit.

Methodology of Treatment:

Study Enrolment:

Patient′s parent or guardian reporting at the OPD with child associated with clinical features of Nocturnal itching, Pruritus papules, Burrow, Papulovesicles, Pustules, Lesions seen in web of hand ,wrists, ulnar aspect of forearm of arm, elbow, axillae, feet, buttock, palms, and sole, genital area. Are chosen for enrolment based on the inclusion criteria. The patients who are enrolled are informed about the study trial drug, possible outcomes and the objectives of the study in the language and terms understandable to them and the informed consent /Assent form would be obtained from the patient / patient's parent or guardian using consent/Assent form.

Conduct of the Study:

On the first day onwards the trial drug *"OMA LEGIUM"* (INTERNAL) *&"MUSUTTAI ENNAI"* (EXTERNAL) will be given. The trial drug will be given in the OPD department of *Kuzhanthai Maruthuvam,* GSMC, Chennai. The patients will be asked to have a regular follow up in the OP department once in 5 days. In each and every visit the clinical assessment will be recorded in the respective forms. The laboratory investigation will be done before and after treatment and recorded in the respective forms.

Data collection forms:

Required information will be collected from each patient by using following forms.

Form I : Screening and selection Performa

Form II : History taking proforma

Form III : Clinical assessment Proforma

Form IV : Clinical assessment during and after trial

Form V : Laboratory Investigation Proforma

Form VI : Informed consent/Assent form

Form VII : Withdrawal form

Form VIII : Patient information sheet

FormIX : Diet sheet

Data Analysis:

After enrolling the patients in the study a separate file for each patient will be maintained and all forms will be kept in the file. Whenever the patient visits OPD during the study period necessary entries will be made in the assessment forms.

The data entries and adverse events if any will be monitored by the Head of the Department.

Outcome of Treatment

Primary Outcome:

Primary outcome is mainly assessed by comparing the reduction in clinical symptoms and recurrence before and after treatment.

Secondary Outcome:

Secondary outcome is assessed by comparing the safety parameters before and after treatment.

Adverse effect and Serious effect Management:

If the trial patient develops any adverse reactions the patient will be referred to the Pharmacovigilance department of SCRI and documented. For any adverse effect the investigator will give the proper management in the OPD.

Ethical issues:

1. Informed consent/Assent will be obtained from the patient / patient's parent or guardian after explaining about the clinical trial in an understandable language.
2. After the consent of the patient (through consent/Assent form) if they fit in the criteria they will be enrolled in the study.
3. Treatment will be provided free of cost.
4. Concomitant medicines will be used if there is any need.
5. The patients who are excluded (as per the exclusion criteria) will be refer to OPD.

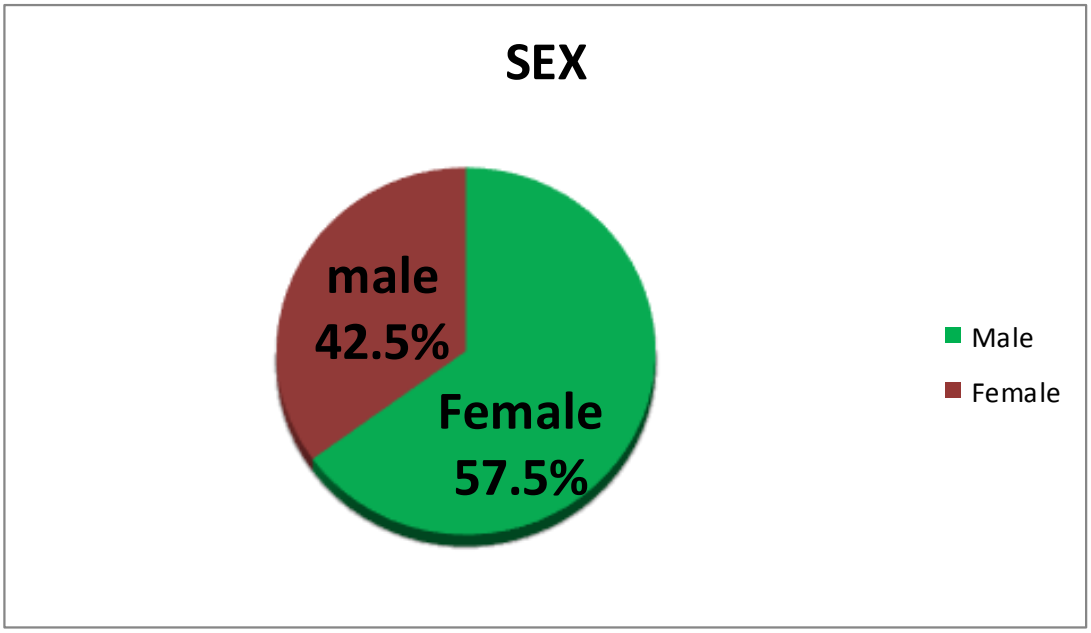
RESULTS AND OBSERVATIONS

The factors considered for the purpose of the study comprised of the following:

- ✶ Sex Distribution
- ✶ Age Distribution
- ✶ Socio economic Status
- ✶ Family History
- ✶ Aetiological Factor
- ✶ Food habits
- ✶ Symptoms
- ✶ Paruvakalam
- ✶ Thinai
- ✶ Classifications of results according to Vali, Azhal& Iyyam
- ✶ Udal Kattugal
- ✶ Ennvagaithervu
- ✶ Naadi
- ✶ Classification on the basis of Neikuri
- ✶ Clinical progress
- ✶ Results after treatment

1. Sex Distribution:

S.No	Sex	No. Of Cases	Percentage
1.	Female	23	57.5%
2.	Male	17	42.5%

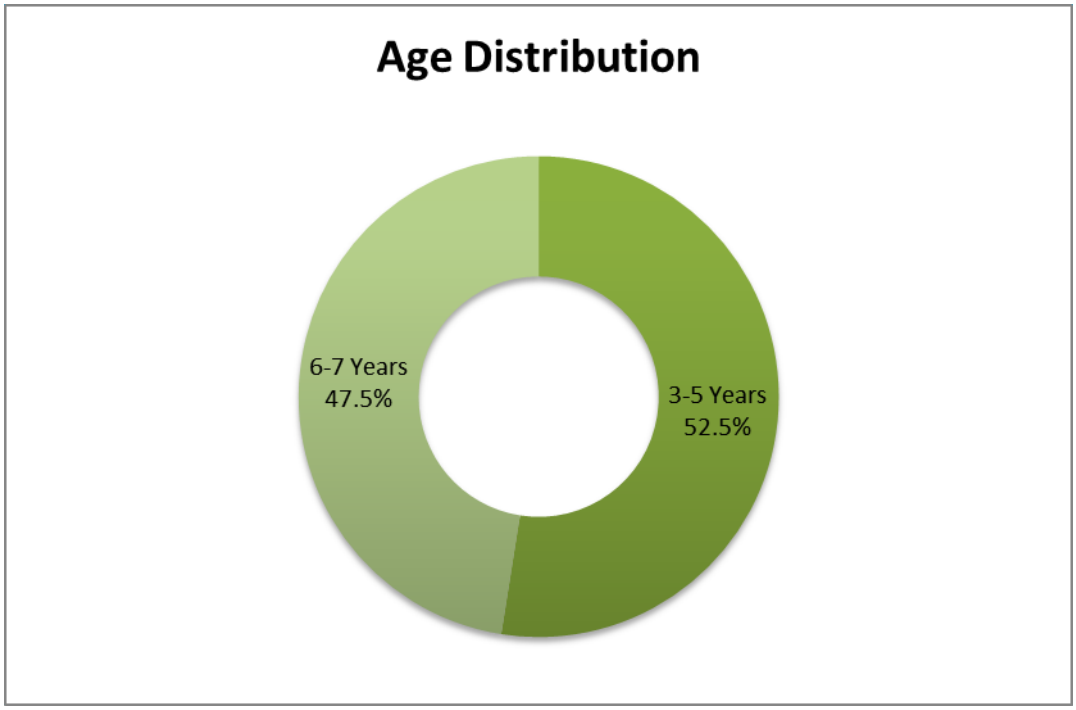


Inference:

Among the 40 patients selected for this study, 57.5% were female children and 42.5% were male children.

2. A**ge Distribution:**

S.No	Age	No. Of Cases	Percentage
1.	3-5 Years	21	52.5%
2.	6-7 Years	19	47.5%

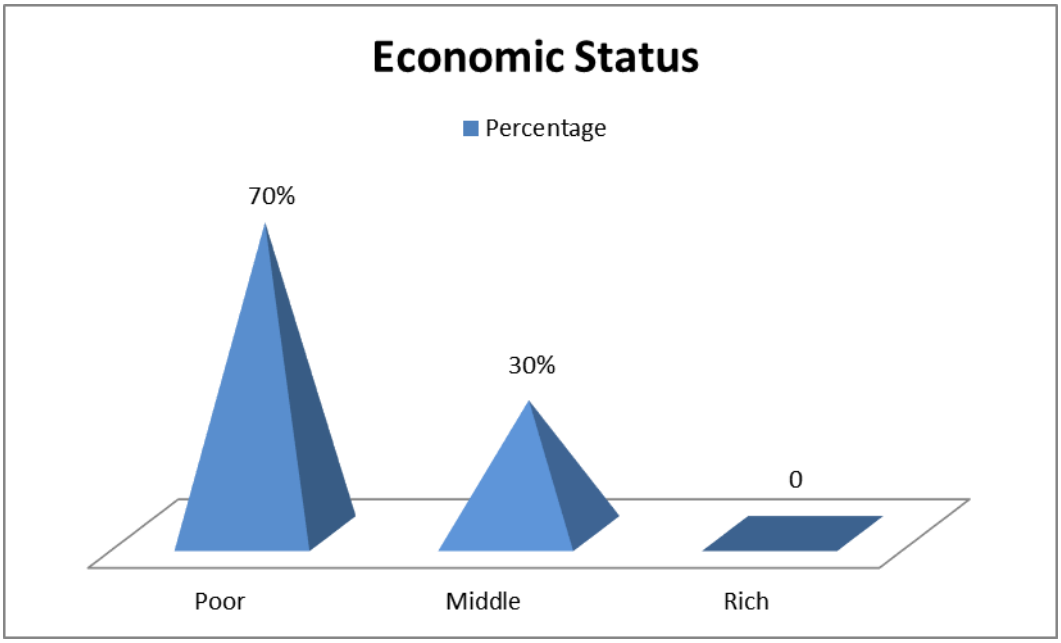


Inference:

Among the 40 patients, maximum numbers of patients 52.5% were in the age group of 3 to 5 year and 47.5% were in the age group of 6 to 7 years,

3. Socio-Economic Status:

S.No	Economic Status	No. Of Cases	Percentage
1.	Poor	28	70%
2.	Middle	12	30%
3.	Rich	0	0

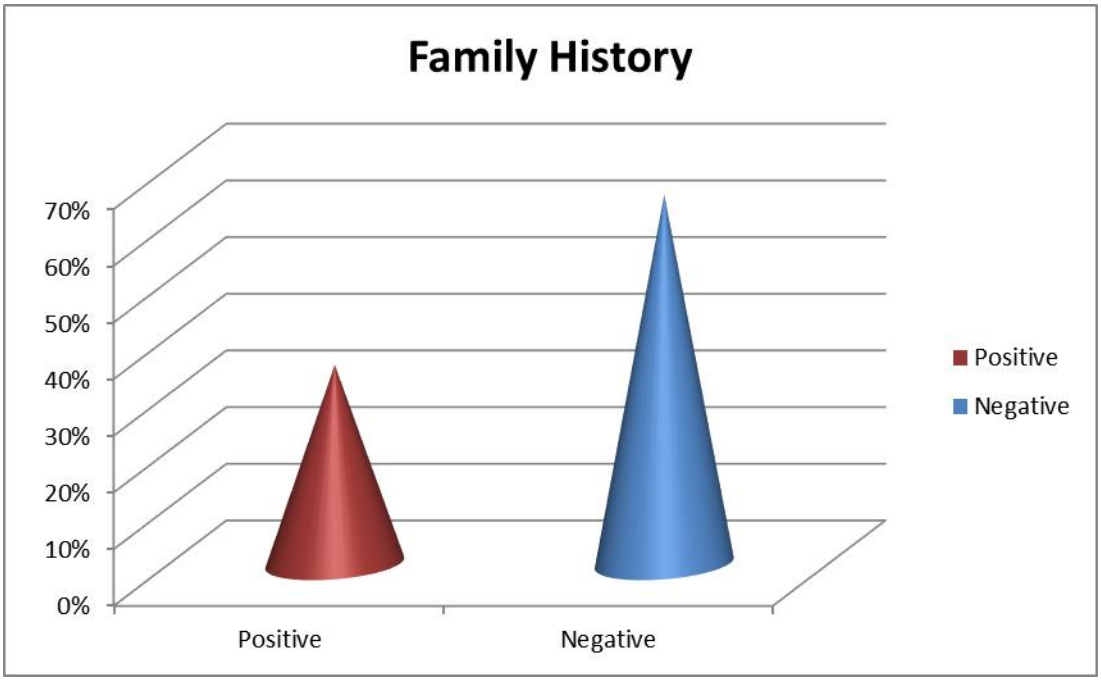


Inference:

Among the 40 patients, 70% were poor status, 30% were in middle status

4. Family History:

S.No	Family History	No. Of Cases	Percentage
1.	Positive	14	35%
2.	Negative	26	65%

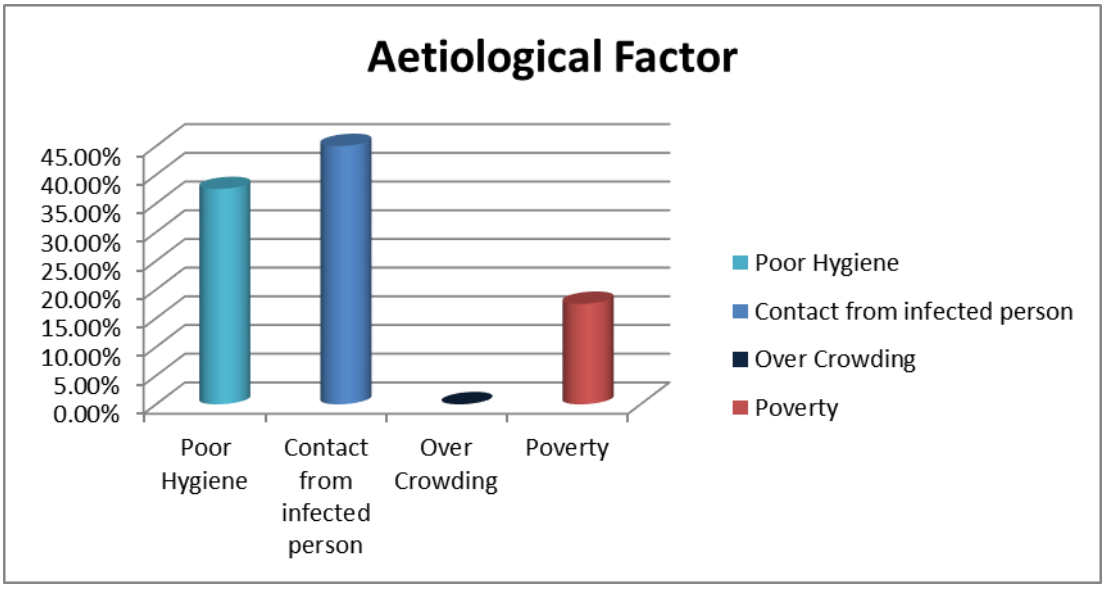


Inference:

Among the 40 patients, 65% of the patients showed negative family history, 35% patients showed positive family history

5. Aetiological Factor:

S.No	Aetiological Factors	No. Of Cases	Percentage
1.	Poor Hygiene	15	37.5%
2.	Contact from infected person	18	45%
3.	Over Crowding	0	0
4.	Poverty	7	17.5%

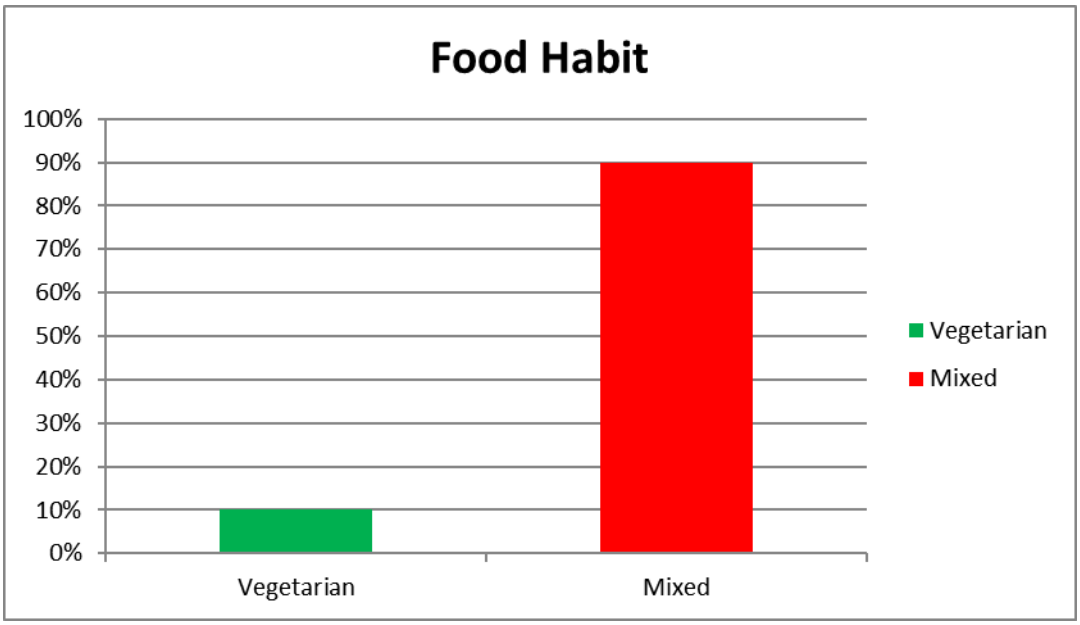


Inference:

Among 40 patients, 45% of the patients showed contact from infected person, 37.5% of the patients showed poor hygiene and 17.5% of the patients showed poverty.

6. Food Habits:

S.No	Food habit	No. Of Cases	Percentage
1.	Vegetarian	4	10%
2.	Mixed	36	90%

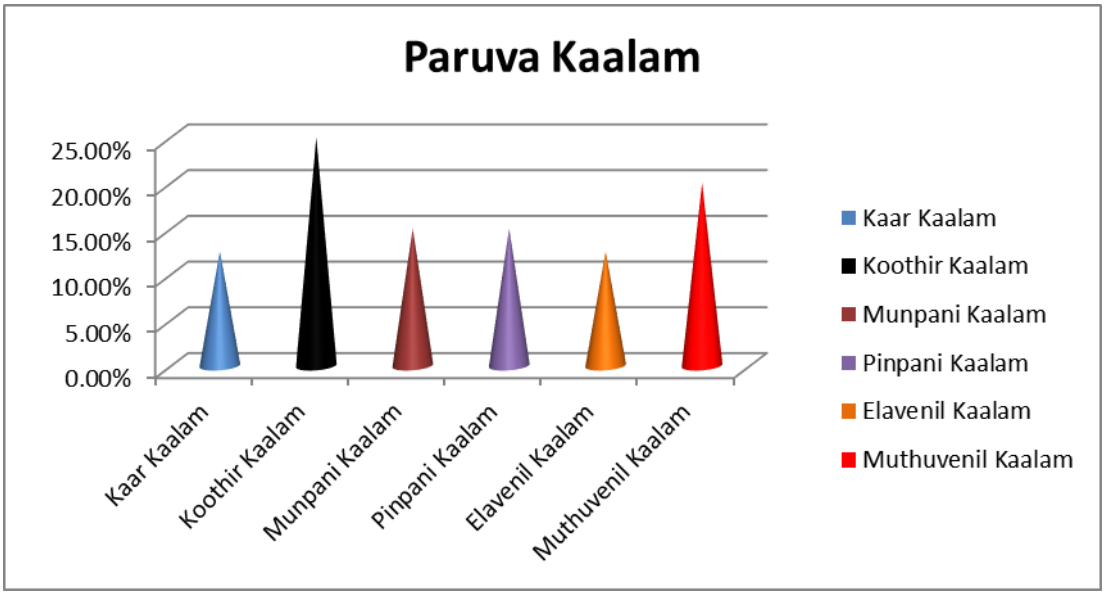


Inference:

Among the 40 patients, 90% of the cases were mixed diet and 10% of the cases were vegetarian.

7. Paruva Kaalam:

S.No	Paruva Kaalam	No. Of Cases	Percentage
1.	Kaar Kaalam	5	12.5%
2.	Koothir Kaalam	10	25%
3.	Munpani Kaalam	6	15%
4.	Pinpani Kaalam	6	15%
5.	Elavenil Kaalam	5	12.5%
6.	Muthuvenil Kaalam	8	20%

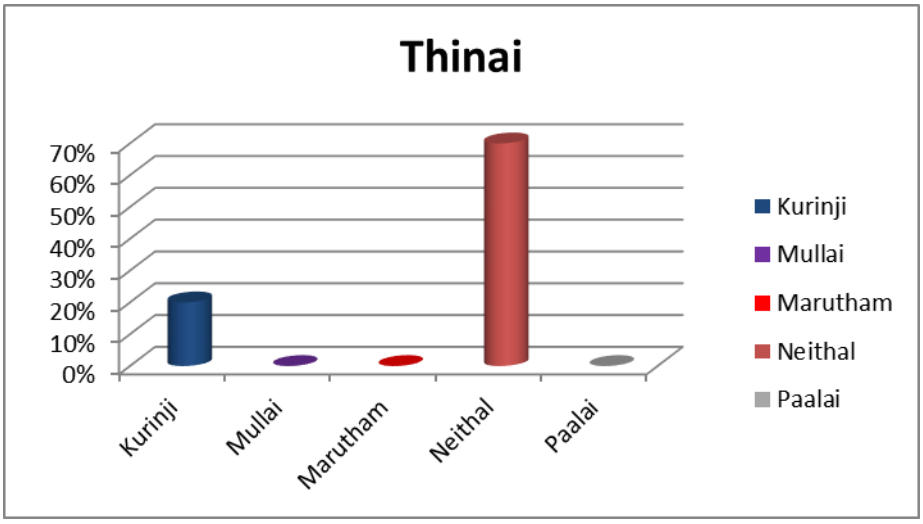


Inference:

Among the 40 patients,12.5% reported in kaarkaalam and Elavenilkaalam, 25% reported in koothir kaalam,15% reported in munpanikaalam and pinpanikaalam ,20% muthuvenilkaalam.

8. **Thinai:**

S.No	Thinai	No. Of Cases	Percentage
1.	Kurinji	12	20%
2.	Mullai	0	0
3.	Marutham	0	0
4.	Neithal	28	70%
5.	Paalai	0	0

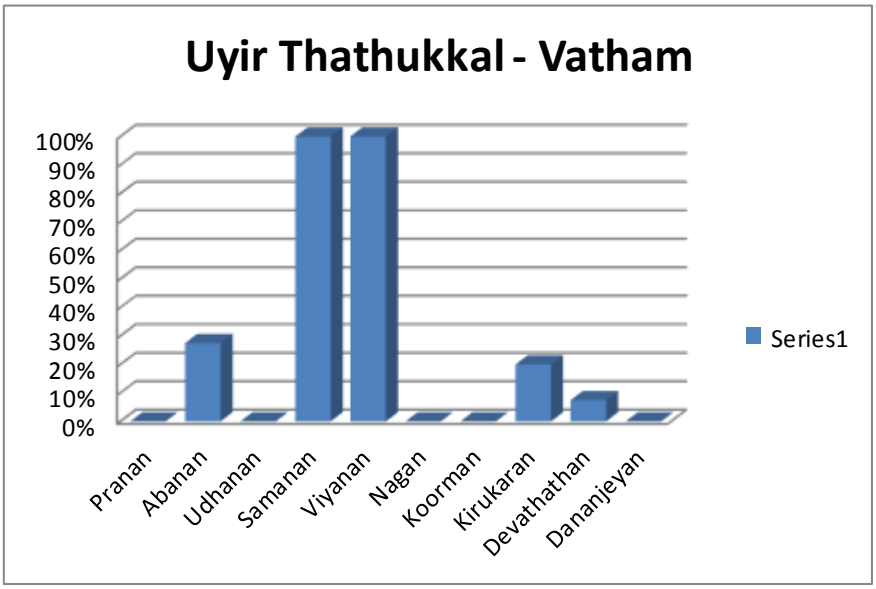


Inference:

Among 40 the patients, 70% of the patients were from neithal, 20% of the patients were from Kurinji.

9. Uyir Thathukkal-Vatham

S.No	Vatham	No. Of Cases	Percentage
1.	Pranan	0	0%
2.	Abanan	11	27.5%
3.	Udhanan	0	0%
4.	Samanan	40	100%
5.	Viyanan	40	100%
6.	Nagan	0	0%
7.	Koorman	0	0%
8.	Kirukaran	8	20%
9.	Devathathan	3	7.5%
10.	Dananjeyan	0	0

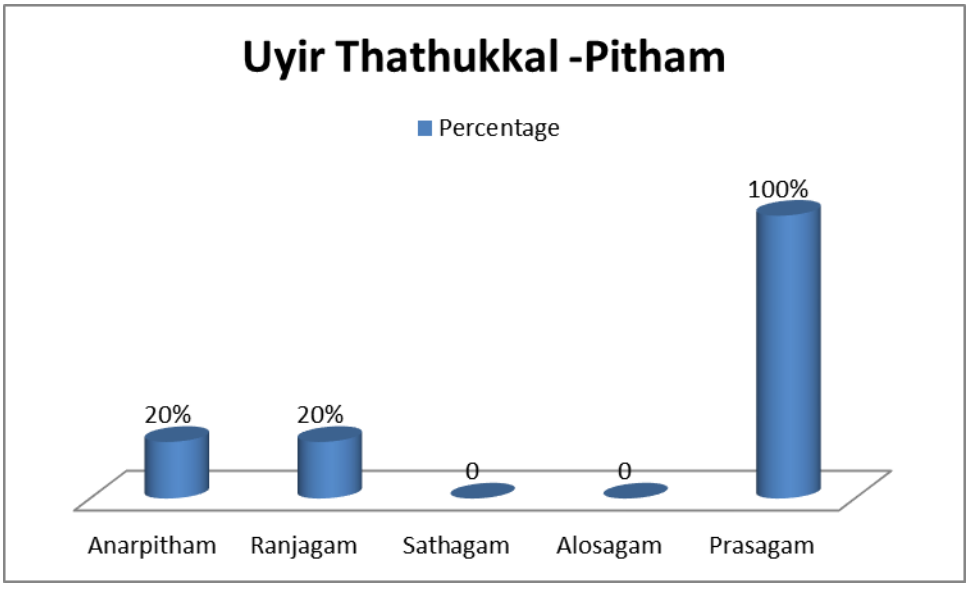


Inference:

Among the 40 patients, Samanan and Viyanan affected 100%, 27.5% affected Abanan, 20% affected Kirukaran, and 7.5% affected Devathathan

10. Uyir Thathukkal-Pitham

S.No	Pitham	No. Of Cases	Percentage
1.	Anarpitham	8	20%
2.	Ranjagam	8	20%
3.	Sathagam	0	0
4.	Alosagam	0	0
5.	Prasagam	40	100%

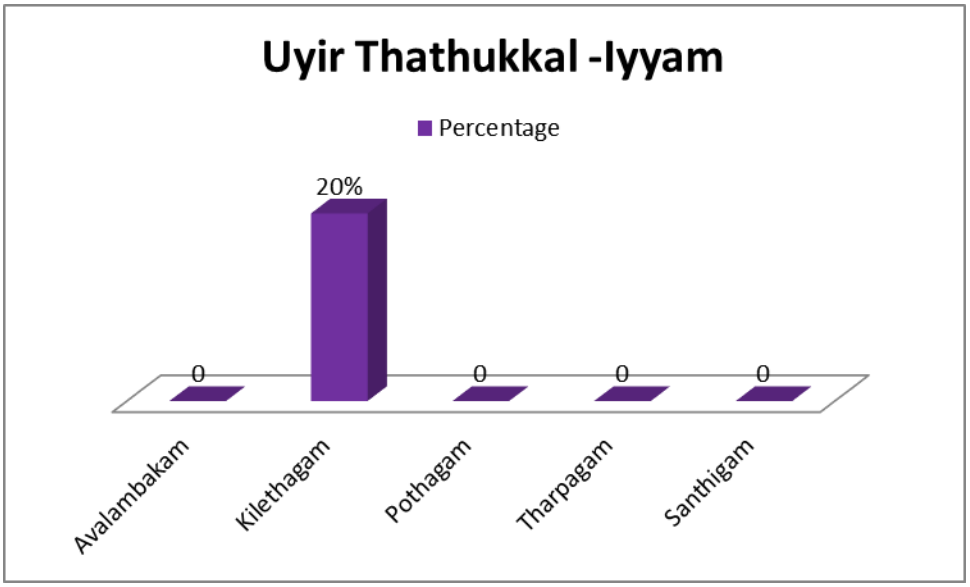


Inference:

Prasagam was affected in all the 40 cases, Anarpitham and Ranjagam was affected 20% of the patients and prasagam was a affected 100% of the patients.

11. Uyir Thathukkal-Iyyam

S.No	Iyyam	No. Of Cases	Percentage
1.	Avalambakam	0	0
2.	Kilethagam	8	20%
3.	Pothagam	0	0
4.	Tharpagam	0	0
5.	Santhigam	0	0

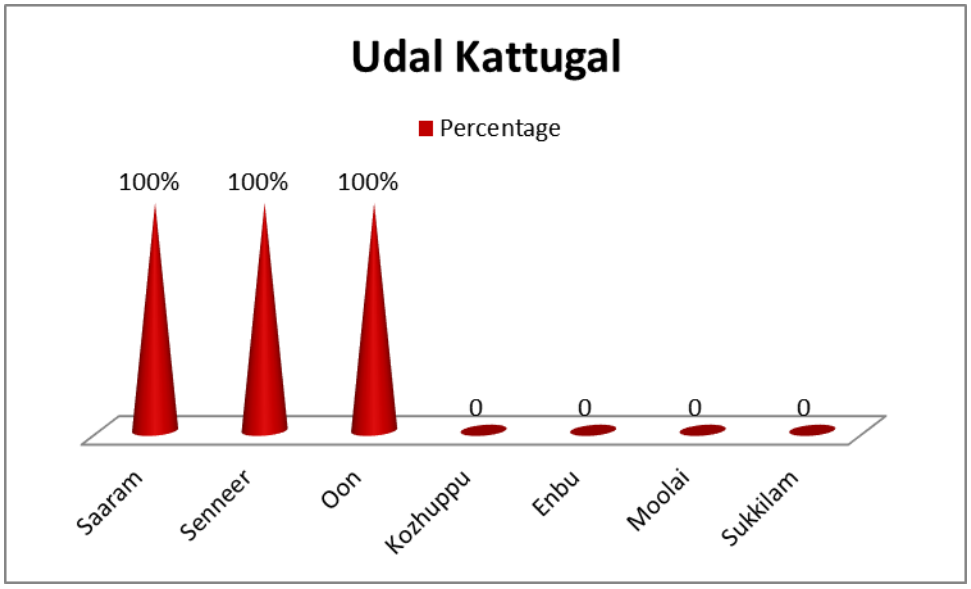


Inference:

Among the 40 patients, 20% of Kilethagam was affected.

12. Udal Kattugal:

S.No	Udal Kattugal	No. Of Cases	Percentage
1.	Saaram	40	100%
2.	Senneer	40	100%
3.	Oon	40	100%
4.	Kozhuppu	0	0
5.	Enbu	0	0
6.	Moolai	0	0
7.	Sukkilam	0	0

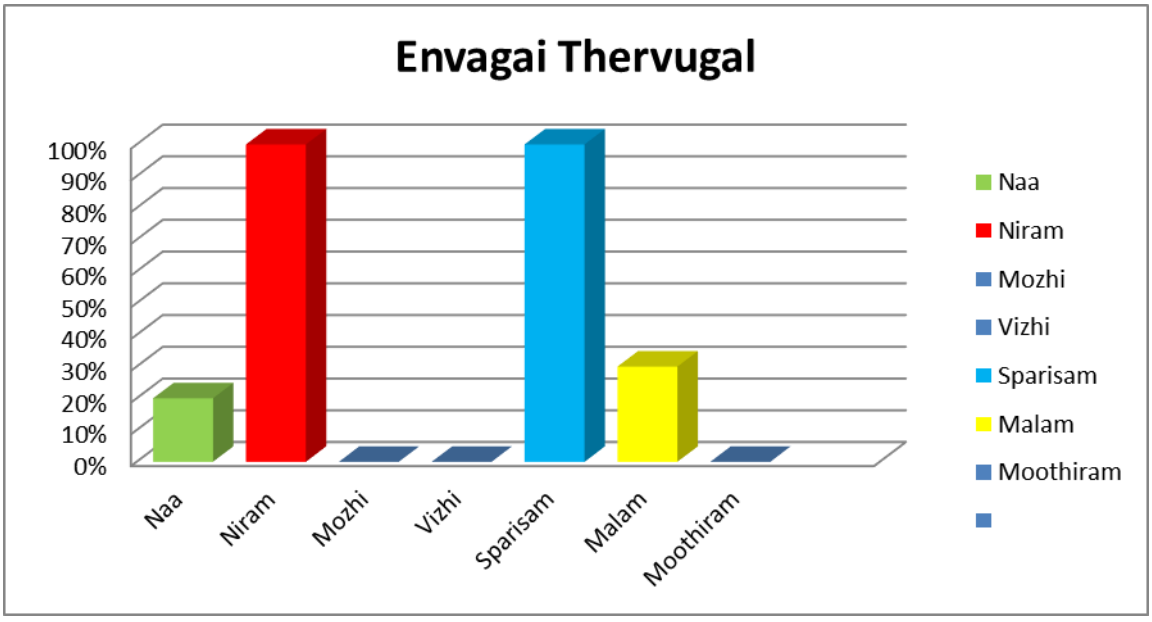


Inference:

Among the 40 patients, Saaram, Sennar, and Oon was affected all the 40 cases.

13. Envagai Thervugal:

S.No	Envagai Thervugal	No. Of Cases	Percentage
1.	Naa	8	20%
2.	Niram	40	100%
3.	Mozhi	0	0%
4.	Vizhi	0	0%
5.	Sparisam	40	100%
6.	Malam	12	30%
7.	Moothiram	0	0%

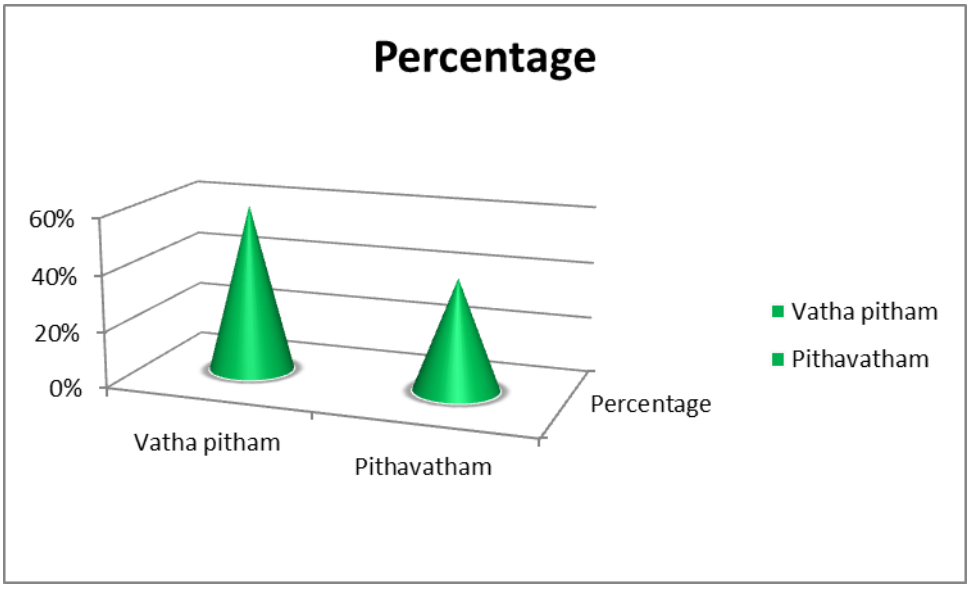


Inference:

Among the 40 patients affected. Niram and Sparisam was affected 100% ,Malam was affected 30% and Naa was affected 20%.

14. Naadi:

S.No	Naadi	No. Of Cases	Percentage
1.	Vatha pitham	24	60%
2.	Pithavatham	16	40%

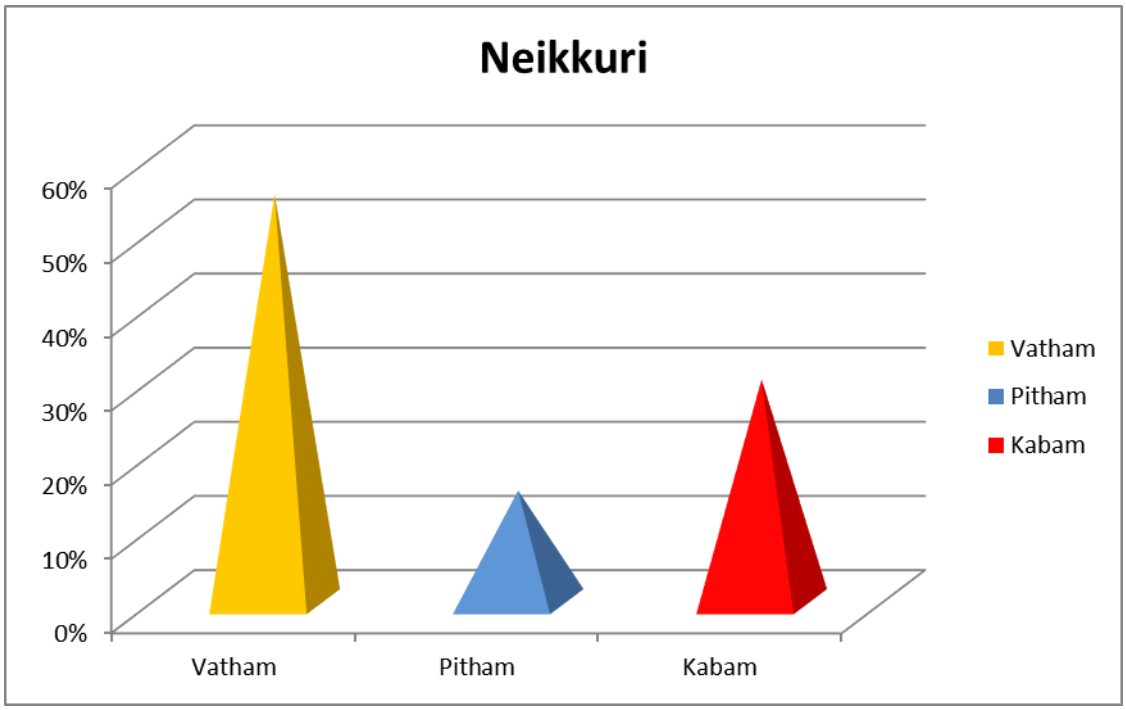


Inference:

Among the 40% patients Vaathapitham60% and Pithavaatham 40%.

15. Neikkuri:

S.No	Neikkuri	No. Of Cases	Percentage
1.	Vatham	22	55%
2.	Pitham	6	15%
3.	Kabam	12	30%

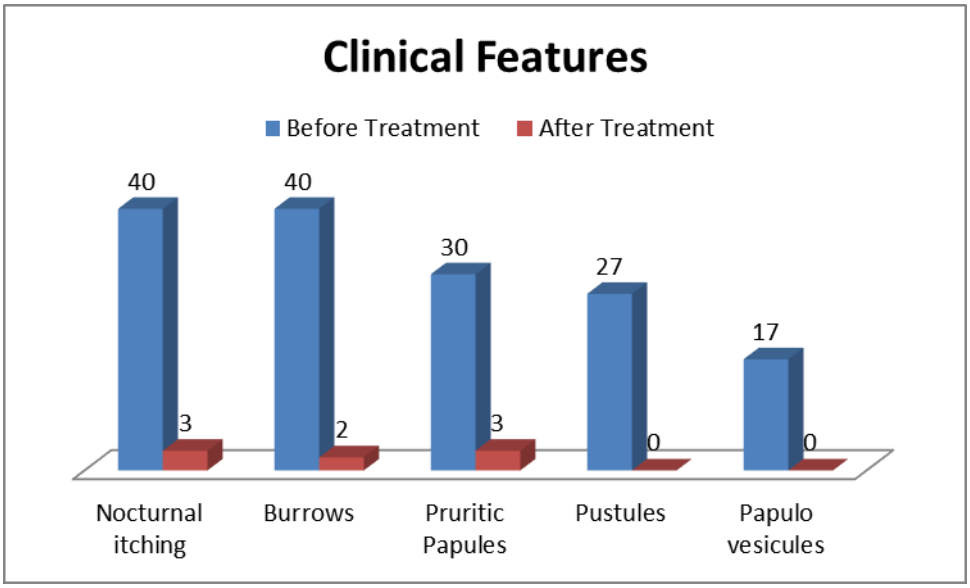


Inference:

Among the 40 patients, 55% cases were having VathamNeikkuri, 30% cases were having kabam Neikkuri, and 15% cases were having Pitham Neikkuri.

16. Clinical Features:

S.No	Clinical Features	Before Treatment No. Of Cases	After Treatment No. Of Cases
1.	Nocturnal itching	40	3
2.	Burrows	40	2
3.	Pruritic Papules	30	3
4.	Pustules	27	0
5.	Papulo vesicules	17	0

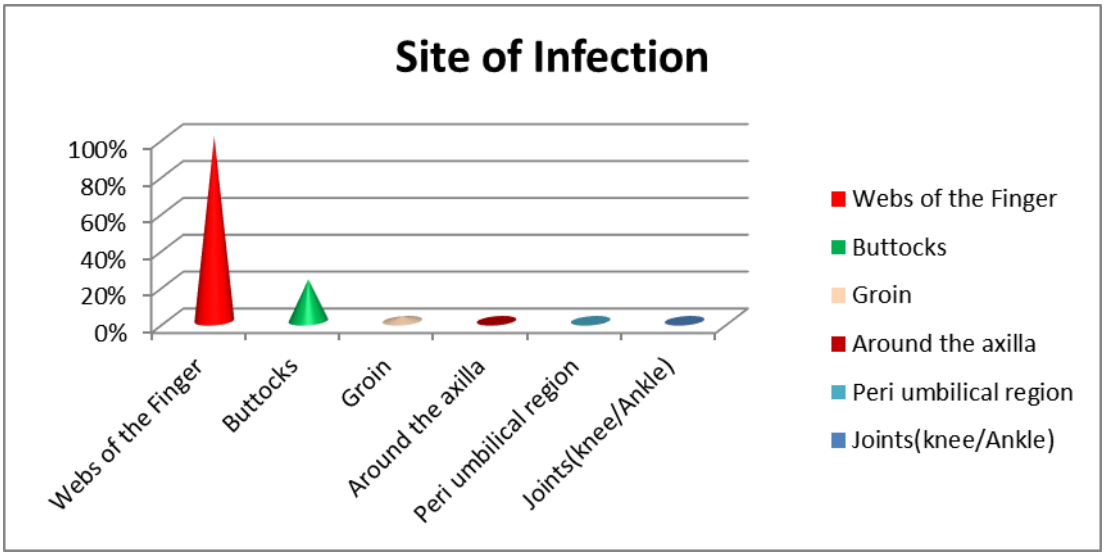


Inference:

Among the 40 patients. 100% of cases have Nocturnal itching and Burrows. 75% of cases have Pruritis papules, 67.5% of cases have pustules, and 42.5% of the cases have Papulo vesicles. After treatment 7.5% of cases have Nocturnal itching and Pruritic papules, 5% of cases have Burrows.

17. Site of Infections:

S.No	Site of Infections	No. of Cases	Percentage
1.	Webs of the Finger	40	100%
2.	Buttocks	9	22.5%
3.	Groin	1	2.5%
4.	Around the axilla	0	0
5.	Peri umbilical region	0	0
6.	Joints(knee/Ankle)	0	0

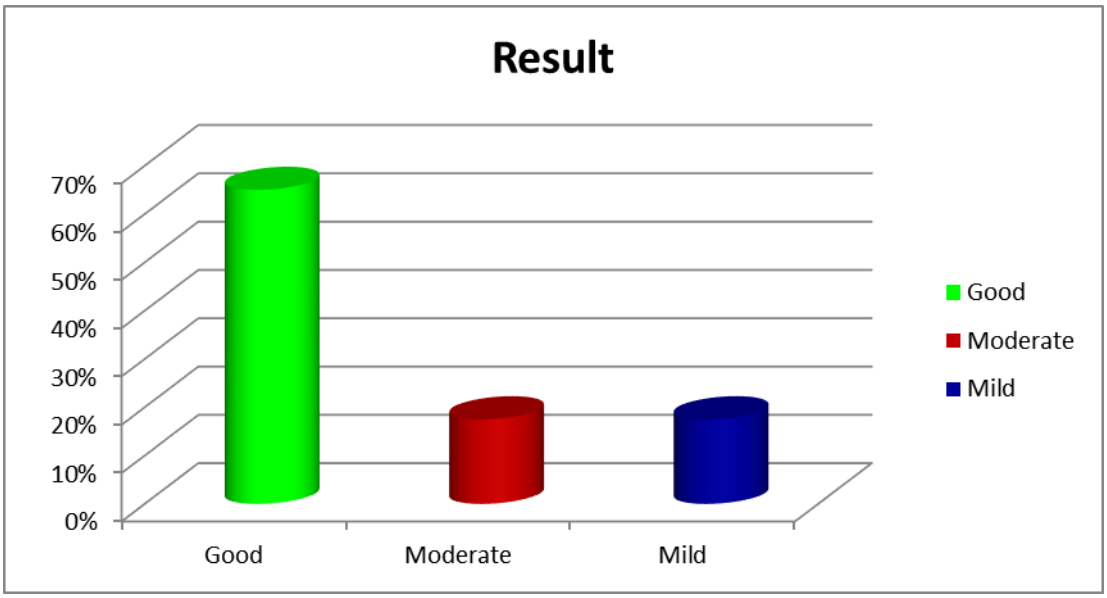


Inference:

Among the 40 patients, 100% Lesion seen in web of finger,22.5% Lesion seen in buttocks and 2.5% Lesion seen in Groin.

18. Result:

S.No	Result	No. Of Cases	Percentage
1.	Good	26	65%
2.	Moderate	7	17.5%
3.	Mild	7	17.5%



Inference:

Among the 40 patients, 65% show good improvement, 17.5% Shown moderate improvement, 17.5% show mild improvement.

LABORATORY INVESTIGATION REPORT OF THE PATIENTS

Si .No.	OP No	Name	Age/ Sex	HAEMATOLOGICAL ANALYSIS													Urine analysis					
				Before treatment				After Treatment				ESR (mm)				Hb (gms %)		BT			AT		
				TC (cu/mm)	DC			TC (cu/mm)	DC			BT		AT									
					P %	L%	E %		P %	L%	E %	½ hr	1 hr	½ hr	1 hr	BT	AT	Alb	Sug	Dep	Alb	Sug	Dep
1	9542	Vishali	3/FC	9800	43	51	6	9700	45	52	3	6	12	5	10	10.2	10.4	N	N	N	N	N	N
2	9541	Visvanathan	4/MC	14500	55	37	8	11000	56	40	4	32	58	15	34	11.9	12	N	N	N	N	N	N
3	9963	Rumarleeka	3.5/FC	12100	46	45	9	9900	53	43	4	22	39	13	20	12.3	10.1	N	N	N	N	N	N
4	8268	Vikneshvaran	7/MC	9100	67	27	6	8600	68	28	4	24	50	12	30	11.6	11	N	N	N	N	N	N
5	2143	Francy	7/FC	9900	56	37	7	9000	59	38	3	20	45	12	26	12.9	13	N	N	N	N	N	N
6	2273	Sanjay Kumar	3/MC	10800	47	48	5	8900	50	46	4	16	25	11	17	12.6	12.8	N	N	N	N	N	N
7	4309	Mohana	5/FC	6700	44	50	6	6500	48	49	3	10	25	7	16	11.6	12	N	N	N	N	N	N
8	5028	Janani	7/FC	7700	41	53	6	7400	50	48	3	14	20	8	13	11.6	11.8	N	N	N	N	N	N
9	6205	Yugalakshmi	6/FC	5500	48	47	5	4900	51	46	3	13	40	7	21	10.9	11	N	N	N	N	N	N
10	6081	Chinidini	6.5/FC	7400	67	30	3	6600	65	32	3	23	45	14	25	12.2	12	N	N	N	N	N	N
11	7470	Jeevanandan	7/MC	7500	47	45	8	7100	49	47	4	4	7	5	10	10	12.3	N	N	N	N	N	N
12	7478	Dayalan	4/MC	8600	56	36	8	8200	59	38	3	8	18	6	15	10.3	10.6	N	N	N	N	N	N
13	7405	Seetha	4/FC	7800	47	45	8	7900	50	46	4	4	10	3	8	11.8	12	N	N	N	N	N	N
14	7187	Dhivyasri	3/FC	13100	58	36	6	12300	60	37	3	5	14	6	13	12.4	12.2	N	N	N	N	N	N
15	3634	Nithishraj	4/MC	8300	45	50	5	7700	47	49	4	5	12	4	10	12.2	12.3	N	N	N	N	N	N
16	5903	Sandiya	7/FC	9100	44	47	9	8400	47	48	5	10	22	5	14	11.8	12	N	N	N	N	N	N
17	6601	Jeevika	7/FC	6300	44	47	9	6400	52	44	4	6	18	5	12	11.1	11.3	N	N	N	N	N	N
18	5057	Karthik	4/MC	7400	51	44	5	7100	52	45	3	3	5	3	4	10.7	10.8	N	N	N	N	N	N
19	9619	Thaniyala	3/FC	8300	43	48	9	7500	46	49	5	5	15	4	13	10.5	10.6	N	N	N	N	N	N
20	8196	Dinesh	7/MC	10,000	71	22	7	8300	76	26	4	12	20	7	12	10.8	11	N	N	N	N	N	N

LABORATORY INVESTIGATION REPORT OF THE PATIENTS

Sl No	OP No	Name	Age/ Sex	Haematological analysis													Urine analysis					
				Before treatment				After Treatment				ESR (mm)				Hb (gms %)		BT			AT		
				TC (cu/mm)	DC			TC (cu/mm)	DC			BT		AT									
					P %	L%	E %		P %	L%	E %	½ hr	1 hr	½ hr	1 hr	BT	AT	Alb	Sug	Dep	Alb	Sug	Dep
21	5202	Asmitha	4/FC	9700	65	30	5	9100	66	31	3	10	18	5	12	11.9	12	N	N	N	N	N	N
22	6133	Srija	7/FC	11700	57	38	5	9300	52	42	6	3	10	3	8	11.4	11.4	N	N	N	N	N	N
23	6741	Sachin	7/MC	7200	58	35	7	6600	61	36	3	5	18	3	7	12.8	12.6	N	N	N	N	N	N
24	6989	Dharun	4/MC	8500	53	38	9	7800	56	40	4	4	7	4	5	10.5	11	N	N	N	N	N	N
25	129	Mageshwari	7/FC	8700	52	40	8	7900	58	38	4	4	10	3	8	12.5	12.8	N	N	N	N	N	N
26	959	Kirthika	5/FC	5800	52	40	8	7100	54	42	4	4	15	3	12	12.3	12.6	N	N	N	N	N	N
27	4643	Sathana	5/FC	9900	62	31	7	7600	65	32	3	12	18	6	12	10.2	10.8	N	N	N	N	N	N
28	5812	Charumathi	7/FC	9900	48	47	5	7000	53	44	3	12	20	8	10	11.7	11.9	N	N	N	N	N	N
29	5975	Dhanush	7/MC	7200	55	40	5	8200	58	38	4	4	12	3	10	11.2	11.4	N	N	N	N	N	N
30	1621	Divya	5/FC	6600	46	46	8	7300	51	45	5	3	12	5	14	12.3	12	N	N	N	N	N	N
31	5121	Simna	5/FC	8500	56	39	5	9100	56	38	6	3	7	3	6	13.7	13.5	N	N	N	N	N	N
32	4864	Inthiradevi	6/FC	9700	48	45	7	7400	51	45	4	3	8	3	8	13.5	13	N	N	N	N	N	N
33	4802	Pramila	5/FC	10,000	46	45	9	6900	48	47	5	3	10	5	12	12.0	10	N	N	N	N	N	N
34	6623	Saravanan	6/MC	11400	63	31	6	6300	66	32	2	22	38	3	5	13.5	13.3	N	N	N	N	N	N
35	6765	Kumar	4/MC	9600	64	30	6	7200	68	29	3	2	5	12	18	13.4	13.6	N	N	N	N	N	N
36	6869	Ansarali	6.5/MC	7900	47	46	7	6600	51	46	3	3	10	6	10	13.2	13	N	N	N	N	N	N
37	6860	Jhoncy	3/FC	6600	64	30	6	7700	67	30	3	5	15	7	14	10.4	10.8	N	N	N	N	N	N
38	3047	Hariswaran	4/MC	7400	57	35	8	7000	62	34	4	16	26	15	32	14	14.1	N	N	N	N	N	N
39	8035	Arun	6/MC	7800	62	32	6	8400	60	35	5	12	25	12	25	10	10.3	N	N	N	N	N	N
40	7833	Shanthi	4/FC	11,500	65	30	5	7100	62	35	3	13	26	10	40	9.1	9.6	N	N	N	N	N	N

BT – Before Treatment, AT – After Treatment, N - Nil.TC – Total Blood Count, DC – Differential Blood Count, P – Polymorphs, L – Leucocytes, E – Eosinophils
3ESR – Erythrocytes Sedimentation Rate, mm – Milli meter Hb – Hemoglobin, Alb – Albumin, Sug – Sugar, Dep – Deposits,

CASE SUMMARY OF THE PATIENTS

(Internal medicine)

SL No	OP : No	Name	Age / Sex	Result
1	9542	Vishali	3/FC	Good
2	9541	Vishvanathan	4/MC	Good
3	9963	Rumarleeka	3 1/2/FC	Good
4	8268	Vikneshvaran	7/MC	Mild
5	2143	Francy	7/FC	Good
6	2273	Sanjay kumar	3/MC	Moderate
7	4309	Mohana	5/FC	Mild
8	5028	Janani	7/FC	Good
9	6205	Yugalakshmi	6/FC	Good
10	6081	Chinidini	6 1/2FC	Moderate
11	7470	Jeevanandan	7/MC	Good
12	7478	Dayalan	4/MC	Good
13	7405	Seetha	4/FC	Mild
14	7187	Dhiviyasri	3/FC	Moderate
15	3634	Nithishraj	4/MC	Mild
16	5903	Sandiya	7/FC	Good
17	6601	Jeevika	7/FC	Mild
18	5057	Karthik	4/MC	Good
19	9619	Thaniyala	3/FC	Good
20	8196	Dinesh	7/MC	Moderate

CASE SUMMARY OF THE PATIENTS
(Internal&External)

Sl No	OP No	Name	Age / Sex	Result
21	5202	Asmitha	4/FC	Moderate
22	6133	Srija	7/FC	Good
23	6741	Sachin	7/MC	Mild
24	6989	Dharun	4/MC	Moderate
25	129	Mageshwari	7/FC	Mild
26	959	Kirthika	5/FC	Moderate
27	4643	Sathana	5/FC	Good
28	5812	Charumathi	7/FC	Good
29	5975	Dhanush	7/MC	Good
30	1621	Divya	5/FC	Good
31	5121	Simna	5/FC	Good
32	4864	Inthiradevi	6/FC	Good
33	4802	Pramila	5/FC	Good
34	6623	Saravanan	6/MC	Moderate
35	6765	Kumar	4/MC	Good
36	6869	Ansarali	61/2/MC	Moderate
37	6860	Jhoncy	3/FC	Good
38	3047	Hariswaran	4/MC	Good
39	8035	Arun	6/MC	Good
40	7833	Shanthi	4/FC	Good

PATIENTS PHOTOS

Name: Rumarleeka
Age/Sex: 3½ / FC
OP. No.: 9963

BEFORE TREATMENT

Name: Rumarleeka
Age/Sex: 3½ / FC
OP. No.: 9963

AFTER TREATMENT

DISCUSSION

Sirangu is the one of most common skin disease in paediatric age group. This disease mostly resembles scabies in modern system. Symptoms of Sirangu Nocturnal itching, Burrows, Pruritis papules, Pustules, Papulo vesicules.In this study 40 cases are treated in OPD of postgraduate department of Kuzhanthai Maruthuvam in Govt. Siddha Medical College, attached to Arignar Anna Hospital of Indian Medicine, Chennai-106,from 2015-2017

The patients were examined on siddha system of diagnosis with help of modern investigations. The patients are treated with the trial drug *Oma Legium* (Internal) and *MusuttaiEnai*(External) for 21days.

The observations are described here.

1. Sex Distribution:

Among the 40 cases 23 patients were female children and 17 patients were male children.Mostly female children affected.

2. Age Distribution:

Among the 40 cases, maximum numbers of patients 52.5% were in the age group of 3 to 5 years, 47.5% were in the age group of 6 to 7 years.

3. Socio Economic status

Among the 40 cases, maximum numbers of patients 70% were in poor status, 30% were in middle class. The highest incidence was observed in poor class children due to poor hygienic, so the poor children are more prone to the disease.

4. Family History

Among the 40 cases, 65% of the patients showed negative family history, 35% patients showed positive family history.

5. Aetiological factors

Among the 40 cases, 45% of the patients showed contact infected person, 37.5% of the patients showed poor hygiene and 17.5% of the patients showed poverty.

6. Dietary Habits

Among the 40 cases, 90% of the cases were mixed diet. 10% of cases were vegetarians.

7. According to Paruvakalam

Among the 40 cases, highest incidence 25% cases were observed in Koothirkalam,20%Muthuvenilkaalam,15% of cases in MunpaniKaalam and PinpaniKaalam12.5% of cases in KaarKaalam and ElavenilKaalam .

8. Distribution of Thinai

Out of 40 cases, highest incidence 70% of cases were from in Neithal thinai and 30% cases were in Kurinji thinai, as per siddha literature Vatham was predominant in neithal nilam so it may aggravate the skin diseases.

9. Uyir Thathukkal

Vatham

Among the 40% cases,Viyanan and Samanan was affected 100%,Abanan was affected in 27.5% of patients, Kirukaran was affected in 20% of patients and Devathathan was affected in 7.5% of patients,

Pitham

Among the 40% cases,Prasakam was affected 100%. Anarpitham and Ranjagamwas affected in 20% of the patients. Prasakam is responsible for complexion of the skin so it was affected in all cases.

Kabam

Out of 40 cases, Kilethagam was affected 20% of the patients.

10. Ezhu Udal Kattugal

Out of 40 patients Saram, Senneer and Oon was affected in all cases.

11. Ennvagai Thervugal

Out of 40 patients,Niram and Sparisam were affected in all the cases, Malam affected in 30% of the patients and Naa affected in 20% of cases. In this study 60% of patients have VathaPithaNaadi and 40% patients have PithaVathaNaadi.

12. Neikuri

Among the 40 cases,55% of patients were having Vatha neer, 30% of patients were having Kaba neer and 15% of patients were having Pitha neer.

13. Clinical Features

Among the 40 patients. 100% of cases have Nocturnal itching and Burrows. 75% of cases have Pruritis papules, 67.5% of cases have pustules, and 42.5% of the cases have Papulo vesicles. After treatment 7.5% of cases have Nocturnal itching and Pruritic papules, 5% of cases have Burrows,

Routine examination of blood and urine were done before and after treatment. In most of the cases (80%) were having elevated ESR and increased eosinophil count and it has decreased after treatment.

15. Phytochemical analysis

The Phytochemical analysis of the trial drug shows that the drug contains Chloride.Phosphate,iron,Alkaloides,Flavonoides,Glycosides,Carbohydrates,Triterpnoids,coumarins,Phenols,Tanin,Saponins,Proteins,Betacyanin.

Qualitative analysis of the Musuttai Ennai presence of Alkaloids.

16. Toxicity study of the drug:

The Acute and Sub-acute toxicity of the trial drug was carried out in Wistar albino rats reveals that the drug has no adverse effects, so it is safe to human beings.

17. Physicochemical analysis:

Loss of Drying at ***105 °C (%)*** **-** 39.43 ± 1.98

Total Ash ***(%)***5 - 66 ± 1.69

PH - 6

Total Reducing sugar ***(%w/v)*** - 22.76 ± 1.09

Total fat content ***(%w/v)*** - 6.75 ± 1.14

shows the safe and effectiveness of the drug Oma Legium.

18. Pharmacological analysis:

Pharmacological analysis showed the internal drug has significant anti-inflammatory, anti-allergic, immune modulatory activity ,Anti microbial activity

19. Statistical Analysis

The preclinical studies of trial medicine statistically analysed and showed significant result.

20. **Results**

Among the 40 patient's good improvement observed in 26 cases (65%), moderate improvement in 7cases (17.5%) and mild improvement in 7cases (17.5%) and no adverse events observed clinically during the course of treatment.

SUMMARY

To study the efficacy of siddha medicine ***OMA LEGIUM***(Internal medicine) and ***MUSUTTAI ENNAI***(External medicine) in the treatment of ***Sirangu***.This disease mostly resembles scabies in modern system. Literature evidences of both Siddha and Modern system were collected and also the ingredients of the trial drug was reviewed as well.

For the clinical study 40 patients were selected based on Inclusion and Exclusion criteria. The study is conducted after the drug being screened by the Screening committee and the trial is also approved by the Institutional Ethical Committee (IEC).

Animal studies are carried out after obtaining proper permission from the Institutional Animal Ethical Committee (IAEC). Forty children with ***SIRANGU*** diagnosed clinically treated in outpatient of Arignar Anna Hospital of Indian Medicine, Chennai-106. They were observed for clinical improvement, laboratory investigation done and treated with trial drug.

Pharmacological analysis showed the internal drug has significant anti-inflammatory, anti-allergic, immune modulatory activity ,Anti microbial activity to improve the Patients quality.

Qualitative analysis of the *Oma Legium* presence of Chloride,Phosphate ,ferrous iron etc. *Musuttai Ennai* presence of Alkaloids.

Physico chemical analysis of the trail drug shows the

Loss of Drying at ***105 °C (%)***-39.43 ± 1.98

Total Ash ***(%)***5.66 ± 1.69

PH - 6

Total Reducing sugar ***(%w/v)*** - 22.76 ± 1.09

, Total fat content ***(%w/v)*** - 6.75 ± 1.14

All the patients were kept under strict dietary control during the treatment. The observation on effect of therapy was encouraging.

The external application gave soothing effect and also moistering the skin.

Among the 40 patient's good improvement observed in 26 cases (65%), moderate improvement in 7 cases (17.5%) and mild improvement in 7 cases (17.5%) and Observation made during the clinical study showed that the trial drug was clinically effective and no adverse effect.

CONCLUSION

Sirangu is one of most common skin disease in paediatric age group and mainly caused by *kirumi*, excessive heat of the body the blood is altered to produce *Sirangu.*

In this clinical study ***OMA LEGIUM*** and ***MUSUTTAI ENNAI*** were taken as Internal & External medicine respectively. In ***OMA LEGIUM*** most of ingredients have Kaippu Suvai, it derangement of mainly Pitham following Vatham and decrease the heat.

Toxicological studies showed no acute and sub-acute toxicity,Pharmacological analysis showed the internal drug has significant anti-inflammatory, anti-allergic, immune modulatory activity ,Anti microbial activity .In Bio chemical analysis iron present it effective for anaemia.

The drug is easily administrable and cost effective. During the clinical study no adverse events were observed.

Statistically it is concluded that the treatment was effective and significant.

Clinical results were found to be significant good improvement was found in 65% of cases, moderate in 17.5% of cases and mild in 17.5% of cases. The Clinical trial conducted in selected patients was satisfactory and encouraging. The trial medicine is effective for *Sirangu* in children.

Through this study the effectiveness of trail drug is conformed and re established by the author.

BIO-CHEMICAL ANALYSIS

PREPARATION OF EXTRACT:

2 gm of the Musuttai Ennai is taken in a 100 ml beaker and 20 ml of distilled water is added. The solution is boiled for 10 minutes, cooled and then filtered. The filtrate is called extract. This fluid is taken for the Bio- Chemical analysis

QUALITATIVE ANALYSIS

S.NO	EXPERIMENT	OBSERVATION	INFERENCE
I.	**TEST FOR ACID RADICALS**		
1.	**Test for Chloride** 2 ml of extract is added with dilute nitric acid till the effervescence ceases. Then 2 ml of silver nitrate solution is added	Absence of white precipitate	Absent
2.	**Test for Phosphate:** 2 ml of the extract is treated with 2ml of Ammonium molybdate solution and 2 ml of concentrated nitric acid	Absence of yellow precipitate	Absent
3.	**Test for Carbonate:** 2 ml of the extract is treated with 2 ml of magnesium sulphate solution	Absence of white precipitate	Absent
4.	**Test for Sulphide:** 1 gm of the substance is treated with 2 ml of concentrated Hydrochloric acid	Absence of Rotten egg smelling	Absent
5.	**Test for Sulphate:** 2ml of the above prepared extract is taken in a test tube to this added 2ml of 4% ammonium oxalate solution	Absence of White precipitate	Absent

6.	**Test for Nitrate** 1 gm of the substance is heated with copper turnings and concentrated sulphuric acid and viewed the test tube vertically down	Absence of Reddish brown gas	Absent
7.	**Test for Nitrite** 3 drops of the extract is placed on a filter paper. On that, 2 drop of Acetic acid and 2 drops of Benzidine solution is placed	Absence of yellowish red colour	Absent
8.	**Test for Borate** 2 pinches of the substance is made into paste by using Sulphuric acid and Alcohol (95%) and introduced into the blue flame	Absence of Green tinged flame	Absent
II	**TEST FOR BASIC RADICALS**		
9.	**Test for copper** One pinch of the substance is made into paste with concentrated Hydrochloric acid in a watch glass and introduced into the Non luminous part of the flame	Absence of Bluish green coloured flame	Absent
10.	**Test for iron** To the 2 ml of extract, 2 ml of Ammonium thiocyanate solution is added.	Absence of blood red colour	Absent
11.	**Test for zinc** To the 2 ml of extract Sodium hydroxide solution is added in drops to excess	Absence of white precipitate	Absent
12.	**Test for calcium** 2 ml of the extract is added with 2 ml of 4 % Ammonium oxalate solution.	Absence of white precipitate	Absent
13.	**Test for magnesium** 2ml of extract sodium hydroxide solution is added in drops to excess	Absence of white precipitate	Absent

14.	**Test for potassium** A pinch of substance is treated with 2 ml of sodium nitrite solution and then treated with 2 ml of Cobalt nitrate in 30% glacial Acetic acid	Absence of yellow precipitate	Absent
15.	**Test for sodium** 2 pinches of the substance is made into paste by using Hydrochloric acid and introduced into the blue flame	Absence of yellow colour flame	Absent
16.	**Test for starch** 2 ml of extract is treated with weak iodine solution	Absence of blue colour	Absent
17.	**Test for reducing sugar** 5 ml of Benedict's qualitative solution is taken in a test tube and allowed to boil for 2 minutes and added 10 drops of the extract and again boiled for 2 minutes. The colour changes are noted	Absence of Green colour	Absent
18.	**Test for tannic acid** The extract is treated with ferric chloride solution	Presence of Blue black precipitate	Absent
19.	**Test of the alkaloids** 2 ml of the extract is treated with 2 ml of Picric acid	Trace yellow colour developed	Present

RESULTS:

The trial drug Musuttai Ennai contains

Basic radicals:

Alkaloids.

II.BIO-CHEMICAL ANALYSIS

PREPARATION OF EXTRACT:

2 gm of the OmaLegiumis taken in a 100 ml beaker and 20 ml of distilled water is added. The solution is boiled for 10 minutes, cooled and then filtered. The filtrate is called extract. This fluid is taken for the Bio- Chemical analysis

QUALITATIVE ANALYSIS

S.NO	EXPERIMENT	OBSERVATION	INFERENCE
I.	**TEST FOR ACID RADICALS**		
1.	**Test for Chloride** 2 ml of extract is added with dilute nitric acid till the effervescence ceases. Then 2 ml of silver nitrate solution is added	white precipitate is formed	Present
2.	**Test for Phosphate:** 2 ml of the extract is treated with 2ml of Ammonium molybdate solution and 2 ml of concentrated nitric acid	yellow precipitate is formed	Present
3.	**Test for Carbonate:** 2 ml of the extract is treated with 2 ml of magnesium sulphate solution	Absence of white precipitate	Absent
4.	**Test for Sulphide:** 1 gm of the substance is treated with 2 ml of concentrated Hydrochloric acid	Absence of Rotten egg smelling	Absent
5.	**Test for Sulphate:** 2ml of the above prepared extract is taken in a test tube to this added 2ml of 4% ammonium oxalate solution	Absence white precipitate	Absent
6.	**Test for Nitrate** 1 gm of the substance is heated with copper turnings and concentrated sulphuric acid and viewed the test tube vertically down	Reddish brown gas is evolved	Absent

7.	**Test for Nitrite** 3 drops of the extract is placed on a filter paper. On that, 2 drop of Acetic acid and 2 drops of Benzidine solution is placed	Absence of yellowish red colour	Absent
8.	**Test for Borate** 2 pinches of the substance is made into paste by using Sulphuric acid and Alcohol (95%) and introduced into the blue flame	Absence of Green tinged flame	Absent
II	**TEST FOR BASIC RADICALS**		
9.	**Test for copper** One pinch of the substance is made into paste with concentrated Hydrochloric acid in a watch glass and introduced into the Non luminous part of the flame	Absence of Bluish green coloured flame	Absent
10.	**Test for iron** To the 2 ml of extract, 2 ml of Ammonium thiocyanate solution is added.	Presence of blood red colour	Present
11.	**Test for zinc** To the 2 ml of extract Sodium hydroxide solution is added in drops to excess	Absence of white precipitate	Absent
12.	**Test for calcium** 2 ml of the extract is added with 2 ml of 4 % Ammonium oxalate solution.	Presence of white precipitate	Absent
13.	**Test for magnesium** 2ml of extract sodium hydroxide solution is added in drops to excess	Absence of white precipitate	Absent
14.	**Test for potassium** A pinch of substance is treated with 2 ml of sodium nitrite solution and then treated with 2 ml of Cobalt nitrate in 30% glacial Acetic acid	Absence of yellow precipitate	Absent

15.	**Test for sodium** 2 pinches of the substance is made into paste by using Hydrochloric acid and introduced into the blue flame	Absence of yellow colour flame	Absent
16.	**Test for starch** 2 ml of extract is treated with weak iodine solution	Absence of blue colour	Absent
17.	**Test for reducing sugar** 5 ml of Benedict's qualitative solution is taken in a test tube and allowed to boil for 2 minutes and added 10 drops of the extract and again boiled for 2 minutes. The colour changes are noted	Absence of Green colour	Absent
18.	**Test for tannic acid** The extract is treated with ferric chloride solution	Absence of Blue black precipitate	Absent
19.	**Test of the alkaloids** 2 ml of the extract is treated with 2 ml of Picric acid	Trace yellow colour developed	Absent

RESULTS:

The trial drug OmaLegium contains

Acid radical:

Chloride. Phosphate.

Basic radicals:

Iron.

ICP-MS- Heavy Metal Analysis

ICP-MS- Heavy Metal Analysis Report

ICP-MS

Inductively Coupled Plasma Mass Spectrometry (ICP-MS): ICP-MS is a type of mass spectrometry that is highly sensitive and capable of the determination of a range of metals and several non-metals at concentration below one part in 1012 (parts per trillion). Samples are decomposed to neutral elements in high temperature argon plasma and analyzed based on their mass to charge ratios. It is an automated, simple and unique quantitative and qualitative analysis. It measures elemental isotopes ratio.

Procedure

Digestion of sample is carried out by transforming 2.5 ml of the sample into a closed beaker and 5 ml of concentrated HNO3 was added and digested to near dryness. 16 M nitric acid was further added each time to the sample and digested until the clear solution was obtained. 5ml of 12 M Hydrochloric acid was added to ensure complete digestion .The digested solution was cooled to room temperature and made to the final volume of 100 ml with deionized water. Sample solutions were then filtered through membrane (0.45micron) filter. Finally, the digested samples were used for metal analysis using inductively coupled plasma Mass Spectrometry (Perkin Elmer DRC-e Model) .Each sample was digested in triplicate. A blank solution was also prepared in a similar manner.

Machine Model: **Agilent 7700 ICPMS**

Sample ID: OL

Element	Concentration (mg/L)	Upper Limit (mg/L)
Cadmium (Cd)	**BDL**	0.299

BDL- Below Detective Level

PHYTOCHEMICAL ANALYSIS

Sample Preparation

Oma Legium (OL) was extracted with hydro alcoholic solvent (Methanol: water) 6:4 and the extract was subjected to the following analysis

Test for alkaloids:

Mayer's Test: To the extract, 2ml of mayer's reagent was added, a dull white precipitate revealed the presence of alkaloids.

1) Test for coumarins:

To 1 ml of extract, 1 ml of 10% sodium hydroxide was added. The presence of coumarins is indicated by the formation of yellow color.

2) Test for saponins:

To 1 ml of the extract, 5 ml of water was added and the tube was shaken vigorously. Copious lather formation indicates the presence of Saponins.

3) Test for tannins:

To the extract, ferric chloride was added, formation of a dark blue or greenish black color showed the presence of tannins.

4) Test for glycosides- Borntrager's Test

Test drug is hydrolysed with concentrated hydrochloric acid for 2 hours on a water bath, filtered and the hydrolysate is subjected to the following tests. To 2 ml of filtered hydrolysate, 3 ml of choloroform is added and shaken, choloroform layer is separated and 10% ammomia solution is added to it. Pink colour indicates presence of glycosides.

5) Test for flavonoids:

To 0.1ml of the test sample about 5 ml of dilute ammonia solution were been added followed by addition of few drops of conc. Sulfuric acid. Appearance of yellow color indicates the presence of Flavonoids.

6) Test for phenols:

Lead acetate test: The extract was taken; 3 ml of 10% lead acetate solution was added. A bulky white precipitate indicated the presence of phenolic compounds.

7) Test for cardial glycosides:Keller-Killani Test:

Plant extract treated with 2 ml glacial acetic acid containing a drop of FeCl3 .A brown colour ring indicates the presence of positive test.

8) Test for steroids:

To the test solution 2ml of chloroform was added with few drops of conc. Sulphuric acid (3ml), and shaken well. The upper layer in the test tube was turns into red and sulphuric acid layer showed yellow with green fluorescence. It showed the presence of steroids.

9) Test for Quinones:

The extracts were treated separately with Alc. KOH solution. Appearance of colors ranging from red to blue indicates the presence of Quinones.

10) Test for Cyanins

A. Aanthocyanin:

To 2 ml of the leaf extract, 1 ml of 2N sodium hydroxide was added and heated for 5 min at 100□C. Formation of bluish green colour indicates the presence of anthocyanin.

B. Betacyanin:

To 2 ml of the leaf extract, 1 ml of 2N sodium hydroxide was added and heated for 5 min at 100□C. Formation of yellow colour indicates the presence of betacyanin.

11) Test for Carbohydrates - Benedict's test

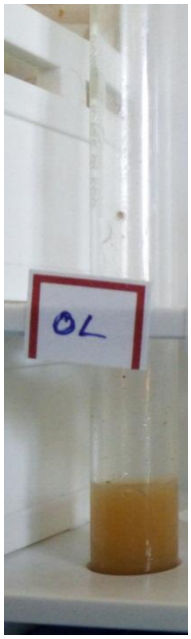
To 0.5 ml of test drug about 0.5 ml of Benedic's reagent is added. The mixture is heated on a boiling water bath for 2 minutes. A characteristic coloured precipitate indicates the presence of sugar.

12) Test for terpenoids:

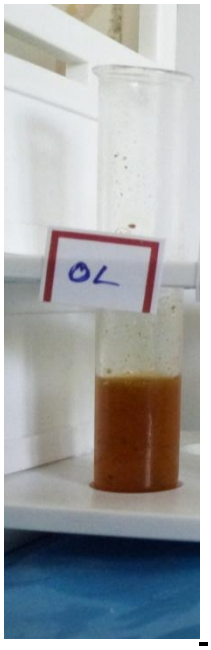
Salkowski test: 5ml of extract was mixed in 2ml of chloroform, and concentrated sulphuric acid was carefully added to form a layer. A reddish brown colouration of the interface indicates the presence of terpenoids.

RESULTS

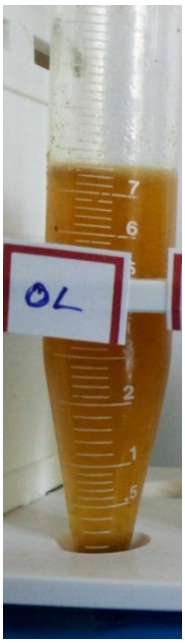
Test for Alkaloids



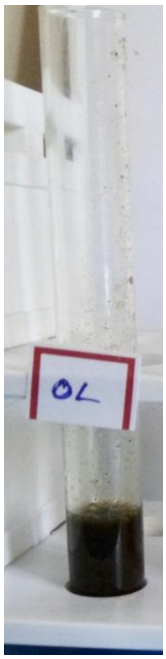
Test for Coumarins



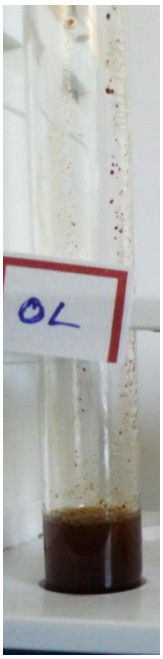
Test for Saponins



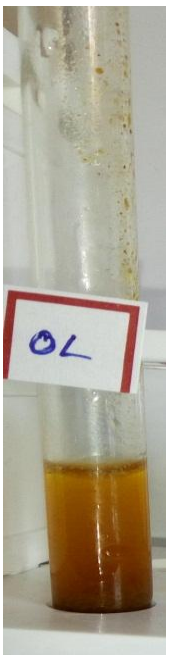
Test for Tanins



Test for Glycosides

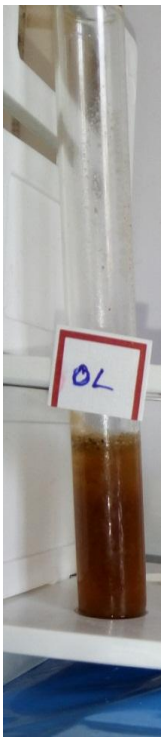


Test for Flavonoids



Test for Phenols

Test for Cardiac Glycosides

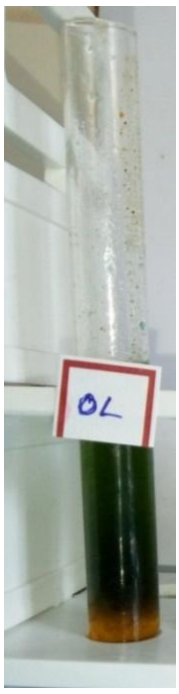


Test for Steroids

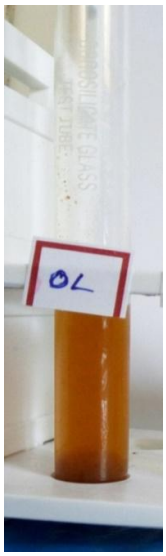
Test for Terpenoids

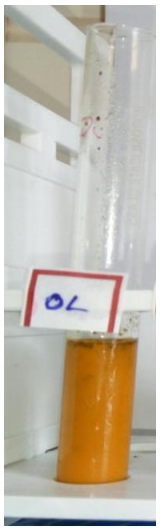
Test for Quinones

Test for Protein



Test for Anthocyanins **Test for Carbohydrates**





Result Analysis

PHYTOCOMPONENTS	OL
ALKALOIDS	+
FLAVONOIDS	+
GLYCOSIDES	+
STEROIDS	-
CARBOHYDRATES	+
TRITEREPNOIDS	+
COUMARINS	+
PHENOLS	+
CARDIAC GLYCOSIDES	-
TANNINS	+
SAPONINS	+
PROTEINS	+
ANTHOCYANIN	-
BETACYANIN	+
QUINONES	-

\+ Indicates positive, - Indicates Negative.

PHYSICOCHEMICAL ANALYSIS

Project ID : NRS/AS/0019/01/2017

Institute : Govt Siddha Medical College

Sample Name : Oma Legium

Sample ID : OL

Percentage Loss on Drying

10gm of test drug was accurately weighed in evaporating dish .The sample was dried at 105^{o}C for 5 hours and then weighed.

Percentage loss in drying = Loss of weight of sample/ Wt of the sample X 100

Determination of Total Ash

3 g of test drug was accurately weighed in silica dish and incinerated at the furnace a temperature 400 ºC until it turns white in color which indicates absence of carbon. Percentage of total ash will be calculated with reference to the weight of air-dried drug.

Total Ash = Weight of Ash/Wt of the Crude drug taken X 100

Determination of PH

About 5 g of test sample will be dissolved in 25ml of distilled water and filtered the resultant solution is allowed to stand for 30 mins and the subjected to pH evaluation

Determination of Total Reducing Sugar Content

20gm wt. equivalent to 20ml of the sample was taken and to which 10ml of conc HCl were added and kept it aside for overnight. Neutralize this solution with approximately 1M NaOH add 10 ml of 21.9 g zinc acetate, 3ml glacial acetic acid followed by 10.6 g potassium ferrocyanide and distilled water was added to make a volume of 100ml. 10ml of Fehling solution was taken and burette solution was added drop wise and heat to boiling over hot plate till blue color appeared. At this time, two drops of methylene blue was added and the titration was carried on till brick red color was obtained

Mg of sugar in 100 ml = Total reducing sugar x 100 / Titer value

Determination of total fat content

Weigh 4gms of sample in the thimble and place it in soxhlet fitted condenser. Take 100 ml of petroleum ether in round bottom flask and boil for 4 hours. Take the extract in pre weighed conical flask and evaporate the petroleum ether on water bath. Remove trace of pet ether with vacuum pump. Take the weight of the residue to constant fat weight.

$$Percentage\ of\ fat\ content = \frac{weight\ of\ petroleum\ ether\ extract\ X\ 100}{weight\ of\ the\ sample\ taken}$$

S.No	Parameter	Mean (n=3) SD
1.	***Loss on Drying at 105 °C (%)***	39.43 ± 1.98
2.	***Total Ash (%)***	5.66 ± 1.69
3.	***Total Reducing sugar (%w/v)***	22.76 ± 1.09
4.	***Total fat content (%w/v)***	6.75 ± 1.14
5.	***pH***	6

Final Test report

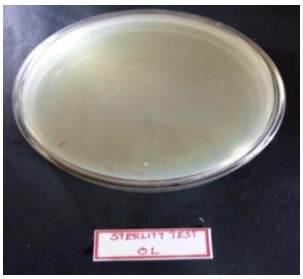
STERILITY TEST BY POUR PLATE METHOD

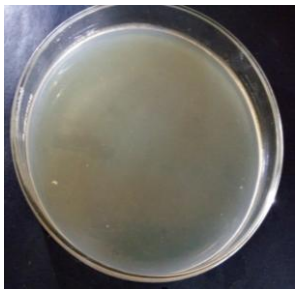
Objective

The pour plate techniques were adopted to determine the sterility of the product. Contaminated / un sterile sample (formulation) when come in contact with the nutrition rich medium it promotes the growth of the organism and after stipulated period of incubation the growth of the organism was identified by characteristic pattern of colonies. The colonies are referred to as Colony Forming Units (CFUs).

Methodology

About 1ml of the test sample was inoculated in sterile petri dish to which about 15 mL of molten agar 45^{o}C were added. Agar and sample were mixed thoroughly by tilting and swirling the dish. Agar was allowed to completely gel without disturbing it. (about 10 minutes). Plates were then inverted and incubated at 37^{o} C for 24-48 hours. Grown colonies of organism was then counted and calculated for CFU.





Observation

No growth was observed after incubation period. Reveals the absence of specific pathogen

Result

No growth / colonies were observed in any of the plates inoculates with the test sample.

Test	Specification	Result	Method
E-coli	Absent	Absent	As per AYUSH specification
Salmonella	Absent	Absent	
Staphylococcus Aureus	Absent	Absent	
Pseudomonas Aeruginosa	Absent	Absent	

Project Report on Toxicity Profiling of *Oma Legium*

Name	Dr. M.SUMATHI
IAEC	SU/CLATR/IAEC/VII/041/2016
Name of the Formulation	***Oma Legium***
Abbreviation	OL

ACUTE TOXICITY STUDY

Acute toxicity study of the study drug *Oma Legium* was carried out as per OECD guideline (Organization for Economic Co-operation and Development) Guideline-423.

Animal

Healthy adult Wistar albino rat weighing between 170-200 g were used for the study. The animals were housed in poly propylene cages and were kept in well ventilated with 100% fresh air by air handling unit (AHU). A 12 light / dark cycle were maintained .Room temperature was maintained between 22 $\pm$ 2^0 C and relative humidity 50–65%. They were provided with food (Sai feeds, Bangalore, India) and water *ad libitum*. All the animals were acclimatized to the laboratory for 7 days prior to the start of the study.

The experimental protocol was approved by The Institutional Animal Ethics Committee of Sathyabama University, Chennai, Tamil Nadu, India.

Acute toxicity Study

Acute toxicity study will be carried out in accordance with OECD guideline 423 [1]. The animals were fasted overnight with free access to water. The study was conducted with single oral dose administration of *Oma Legium*.

IAEC SU/CLATR/IAEC/VII/041/2016

Animal Grouping

One group consist of 6 female rats were used for this study. The dose utilized for evaluation of acute toxicity study is about 2000 mg/kg higher than that of the therapeutic dose.

Animal Grouping

GROUP I : Animals received Test drug 2000 mg/kg (p.o)

The animals were fasted overnight (12- 16 hrs) with free access to water. The study was conducted with single oral administration of study drug *Oma Legium* 2000mg/kg (p.o). The animals were observed continuously for first 72 h and then 14 days for emerging signs of behavioral changes, body weight changes and for mortality.

Occurrence of toxicity in animals were observed continuously for the first 4 to 24 h and observed periodically for the next 14 days. Observation includes the change in skin, fur, eyes and mucus membrane. Appearance of C.N.S,C.V.S and A.N.S related toxicity such as tremors, convulsions, sedation, steric behavior, respiratory distress, cardiovascular collapse, response to sensory stimuli, salivation, diarrhea, lethargy, sleep, coma and mortality were observed with special attention.

Body weight was recorded periodically. At the end of the experiment all animals were subjected for gross necropsy and observed for pathological changes.

SUB-ACUTE TOXICITY STUDY

Sub-acute toxicity study was carried out as per OECD guidelines Guideline-407.

Animals

Healthy adult Wistar albino rat weighing between 170-200 g were used for the study. The animals were housed in poly propylene cages and were kept in well ventilated with 100% fresh air by air handling unit (AHU). A 12 light / dark cycle were maintained .Room temperature was maintained between 22 $\pm$ 2^{o} C and relative humidity 50–65%. They were provided with food (Sai feeds, Bangalore, India) and water *ad libitum*. All the animals were acclimatized to the laboratory for 7 days prior to the start of the study.

The experimental protocol was approved by The Institutional Animal Ethics Committee of Sathyabama University, Chennai, Tamil Nadu, India.

IAEC SU/CLATR/IAEC/VII/041/2016

Animal Grouping

Animals were divided into three groups of 06 animals each consist of 3 male and 3 female rats.

GROUP I **:** Animals received saline 5 ml/kg b.w (p.o)

GROUP II **:** Animals received low dose of test drug 200 mg/kg (p.o)

GROUP III **:** Animals received high dose of test drug 400 mg/kg (p.o)

The animals were randomly divided into control group and drug treated groups for two different doses viz. low dose (200 mg/kg b.w) and high dose (400 mg/kg b.w).

The animals were administrated with the study drug once daily for 28 days. The animals in group I (control group) received normal saline 5 ml/kg b.w. The animals in group II received low dose of *Oma Legium* 200 mg/kg b.w (p.o) and group III received high dose of *Oma Legium* 400 mg/kg b.w (p.o).

The rats were weighed periodically and observed for signs of toxicity pertains to C.N.S, C.V.S, A.N.S including behavioral changes, food - water intake and morphological changes. At the end of 28^{th} day, the animals were fasted for overnight with free access to water. On 29^{th} day the animals were sacrificed with excess anesthesia. Blood samples were collected from aorta and stored in EDTA (ethylenediamine –tetra actate) for Hematological analysis and for serum generation for biochemical analysis.

The vital organs including heart, brain, lungs, spleen, kidneys, liver, stomach, testes, and ovary were harvested and carefully examined for gross lesions. The organs were preserved in 10% formalin for histopathological assessment and interpretation.

Hematological analysis

Blood samples were analyzed using established procedures and automated Bayer Hematology analyzer. Parameters evaluated include Packed Cell Volume (PCV), Red Blood Cells (RBC) count, White blood cell count (WBC), Platelet Count, Hemoglobin (Hb), Mean cell Haemoglobin Concentration (MCHC), Mean Red Cell Volume (MCV), Mean Cell Hemoglobin (MCH), Mean platelet volume (MPV), Neutrophils, Eosinophil's, Basophils, Lymphocytes and Monocytes.

Biochemical analysis [3]

Serum samples were analyzed for High Density Lipoprotein (HDL), Low density Lipoprotein (LDL) , Very low density Lipoprotein (VLDL) , Triglycerides (TGL), Total Cholesterol , Blood urea nitrogen (BUN), Creatinine, Albumin, Total Protein, Glucose, Uric acid, Aspartate Transaminase (AST), Alanine amino Transaminase (ALT) and Alkaline Phosphatase (ALP) using Mind ray auto analyzer model BS 120.

Histopathological evaluation [4]

Organs included of heart, brain, lungs, spleen, kidneys, liver, stomach, testes and ovary. Histological slides of organs were made and observed under the microscope. The pathological observations of cross section of these organs were performed on gross and microscopic bases. Histological examinations were performed on the preserved tissues with particular emphasis on those which showed gross pathological changes.

Statistical analysis

The statistical analysis was carried by one way ANOVA (GRAPH PAD PRISM 5 computer program). Results were expressed as mean ± standard error .A statistical comparison was carried out using the Dunnet's test for the control and treatment group.

Fecal Pellet Analysis

Methodology

Rats of control and treatment group were allowed to explore to open field on clean and sterile Stainless steel tray. The collected pellets were analyzed for consistency, color, Shape, Presence of blood cells etc

Acute Toxicity Study	
Analysis	**Group I**
Consistency	Soft
Shape	Oblong
Colour	Dark Brown
Mucous Shedding	Absence
Blood Cells	Absent
Signs of Infection	None Observed

Sub-Acute Toxicity Study			
Analysis	**Group I**	**Group II**	**Group III**
Consistency	Soft	Soft	Soft
Shape	Oblong	Oblong	Rectangular
Colour	Greenish	Greenish	Greenish
Mucous Shedding	Absence	Absence	Absence
Blood Cells	Absent	Absent	Absent
Signs of Infection	None Observed	None Observed	None Observed

Muscle Grip Strength Analysis: The grip strength test is a simple non-invasive method designed to evaluate rat muscle force in vivo. Rats of control and drug treated group was allowed to hold the pull bar with both the hind limbs firmly then the animal was gently pulled back with the tail until the animal lost the grip toward the bar. The procedure was repeated to get the average value. Muscle grip ness of the drug treated group was compared to that of the control rat to ensure the change in coordination.

Metabolic Cage for Urine Collection

Rat of control and treatment group was placed individually in metabolic cage with free access to feed and water. Urine dropping from the animal was collected using specialized wire mesh system fixed at the base of the cage having provision to trap the fecal pellet mixed with urine sample. The collected urine sample was subjected to analysis with respect to colour, pH, glucose, ketone bodies, pus and blood cells.

RESULTS

Assessment of clinical signs in rats treated with *Oma Legium* on Acute toxicity study

Acute	
Parameter	**Group I**
Clinical Signs Parameters for the duration of 14 days	Test Drug 2000mg/kg
Number of animals observed	6 Female
Lacrimation	Absence
Salivation	Absence
Animal appearance	Normal
Tonic Movement	Absence
Clonic Movement	Absence
Laxative action	Absence
Touch Response	Normal
Response to Sound	Normal Response
Response to Light	Normal Response
Mobility	Normal Response
Respiratory Distress	Nil
Skin Color	Normal
Stereotype behavior	Absence
Piloerection	Absence
Limb Paralysis	Absence
Posture	Normal
Open field behavior	Normal
Giat Balancing	Normal
Freezing Behaviour	Absent
Sings of Stress and Anxiety	None Observed
Muscular coordination	Normal
Muscle grip	Normal

Sedation	Absence
Social Behavior	Normal
Urine Analysis	No Abnormality
Urine Colour	Yellowish
Urine pH	6
Urine -Glucose	Absence
Urine -Ketones	Absence
Urine- Bilirubin	Absence
Urine-Blood Cells	Negative
Urine - Pus cells	Negative
Mortality	Nil

Quantitative data on the body weight of rats treated with *Oma Legium* in Acute toxicity study

Group I	**Before Treatment Weight in Gms**	**After Treatment Weight in Gms**
Mean	180	191.8
Std. Deviation	6.542	8.256
Std. Error	2.671	3.371

Values are mean ± S.D (n = 6 per group). Statistical significance carried out using one way ANOVA followed by Dunnett's test.

Assessment of clinical signs in rats treated with *Oma Legium* on Sub-Acute toxicity study

SUB ACUTE			
Parameters	**Group I**	**Group II**	**Group III**
Clinical Signs Parameters for the duration of 28 days	Control	Test Drug 200mg/kg	Test Drug 400mg/kg
Number of animals observed	3 Males and 3Females	3 Males and 3Females	3 Males and 3Females
Lacrimation	Absence	Absence	Absence
Salivation	Absence	Absence	Absence
Animal appearance	Normal	Normal	Normal
Tonic Movement	Absence	Absence	Absence
Clonic Movement	Absence	Absence	Absence
Laxative action	Absence	Absence	Absence
Touch Response	Normal	Normal	Normal
Response to Sound	Normal Response	Normal Response	Normal Response
Response to Light	Normal Response	Normal Response	Normal Response
Mobility	Normal Response	Normal Response	Normal Response
Respiratory Distress	Nil	Nil	Nil
Skin Color	Normal	Normal	Normal
Stereotype behavior	Absence	Absence	Absence
Piloerection	Absence	Absence	Absence
Limb Paralysis	Absence	Absence	Absence
Posture	Normal	Normal	Normal
Open field behavior	Normal	Normal	Normal
Giat Balancing	Normal	Normal	Normal
Freezing Behaviour	Absent	Absent	Absent

Sings of Stress and Anxiety	None Observed	None Observed	None Observed
Muscular coordination	Normal	Normal	Normal
Muscle grip	Normal	Normal	Normal
Sedation	Absence	Absence	Absence
Social Behavior	Normal	Normal	Normal
Urine Analysis	No Abnormality	No Abnormality	No Abnormality
Urine Colour	Yellowish	Yellowish	Yellowish
Urine pH	6	7	7
Urine -Glucose	Absence	Absence	Absence
Urine -Ketones	Absence	Absence	Absence
Urine- Bilirubin	Absence	Absence	Absence
Urine-Blood Cells	Negative	Negative	Negative
Urine - Pus cells	Negative	Negative	Negative
Mortality	Nil	Nil	Nil

Effect of *Oma Legium* on Body weight of Rats in Sub-acute toxicity study

Group I	**Before Treatment Weight in Gms**	**After Treatment Weight in Gms**
Mean	184	195.5
Std. Deviation	5.177	5.958
Std. Error	2.113	2.432
Group II	**Before Treatment Weight in Gms**	**After Treatment Weight in Gms**
Mean	176.7	189.5
Std. Deviation	4.227	3.674
Std. Error	1.726	1.5
Group III	**Before Treatment**	**After Treatment Weight in Gms**
Mean	183.8	194.5
Std. Deviation	5.845	5.01
Std. Error	2.386	2.045

Values are mean ± S.D (n = 6 per group of which 3 males and 3 females). Control and treatment groups were compared statistically using one way ANOVA followed by Dunnett's test.

Quantitative data on the food and water intake of rats treated with *Oma Legium* for 28 days in Sub-acute toxicity study

GROUP I	**Food intake**	**Water intake**
Mean	17.42	22.25
Std. Deviation	3.573	6.437
Std. Error	1.787	3.219
GROUP II	**Food intake**	**Water intake**
Mean	15	29.25
Std. Deviation	2.126	1.524
Std. Error	1.063	0.7622
GROUP III	**Food intake**	**Water intake**
Mean	16.5	22.58
Std. Deviation	2.285	2.754
Std. Error	1.143	1.377

Values are mean ± S.D (n = 6 per group of which 3 males and 3 females). Control and treatment groups were compared statistically using one way ANOVA followed by Dunnett's test.

Effect of *Oma Legium* on Haematology profile of rats in sub-acute toxicity study.

GROUP I	**WBC count (×103 µl)**	**RBC (×10 ^{6} µl)**	**PLT (×10 ^{3} µl)**	**MCV (fl)**	**MCH (pg)**	**MCHC (g/dl)**	**HGB (g/dl)**
Mean	9.933	6.6	679.8	58.83	19.22	32.75	13.27
Std. Deviation	1.483	1.103	174.3	6.218	2.232	1.299	1.089
Std. Error	0.6053	0.4502	71.15	2.538	0.9112	0.5303	0.4447
GROUP II	**WBC count (×103 µl)**	**RBC (×10 ^{6} µl)**	**PLT (×10 ^{3} µl)**	**MCV (fl)**	**MCH (pg)**	**MCHC (g/dl)**	**HGB (g/dl)**
Mean	10.98	6.867	824.5	64.52	19.55	31.53	13.33
Std. Deviation	1.757	1.007	105.6	4.59	2.091	2.161	1.275
Std. Error	0.7171	0.4112	43.1	1.874	0.8535	0.8823	0.5207
GROUP III	**WBC count (×103 µl)**	**RBC (×10 ^{6} µl)**	**PLT (×10 ^{3} µl)**	**MCV (fl)**	**MCH (pg)**	**MCHC (g/dl)**	**HGB (g/dl)**
Mean	10.52	6.4	775.7	59.25	18.02	32.72	12.52
Std. Deviation	1.775	1.304	154.4	5.377	2.576	1.412	0.9827
Std. Error	0.7245	0.5323	63.03	2.195	1.052	0.5764	0.4012

Values are mean ± S.D (n = 6 per group of which 3 males and 3 females). Control and treatment groups were compared statistically using one way ANOVA followed by Dunnett's test.

Effect of *Oma Legium* on Haematology profile of rats in sub-acute toxicity study.

GROUP I	**Lymph (%)**	**Mon (%)**	**Neutrophils 10^3/mm3**	**Eosinophils (%)**	**Basophils (%)**	**MPV (fl)**
Mean	80.92	3.6	2.5	1.667	0.1667	5.833
Std. Deviation	6.151	0.9033	0.6033	0.2251	0.4082	1.14
Std. Error	2.511	0.3688	0.2463	0.09189	0.1667	0.4652
GROUP II	**Lymph (%)**	**Mon (%)**	**Neutrophils 10^3/mm3**	**Eosinophils (%)**	**Basophils (%)**	**MPV (fl)**
Mean	72.78	3.517	2.05	1.65	0.3333	5.733
Std. Deviation	10.86	1.283	0.3146	0.2881	0.5164	0.8214
Std. Error	4.433	0.5237	0.1285	0.1176	0.2108	0.3353
GROUP III	**Lymph (%)**	**Mon (%)**	**Neutrophils 10^3/mm3**	**Eosinophils (%)**	**Basophils (%)**	**MPV (fl)**
Mean	70.3	2.433	2.3	1.617	0	4.783
Std. Deviation	3.422	0.871	0.502	0.2137	0	0.5776
Std. Error	1.397	0.3556	0.2049	0.08724	0	0.2358

Values are mean ± S.D (n = 6 per group of which 3 males and 3 females). Control and treatment groups were compared statistically using one way ANOVA followed by Dunnett's test.

Effect of *Oma Legium* on Serum Bio-chemistry profile of rats in sub-acute toxicity study

GROUP I	**Blood sugar (mg/dl)**	**BUN (mg/dl)**	**Serum creatinine (mg/dl)**	**Serum total cholesterol (mg/dl)**	**Serum triglycerides level (mg/dl)**	**Serum HDL cholesterol (mg/dl)**	**Serum LDL cholesterol (mg/dl)**	**Serum VLDL cholesterol (mg/dl)**
Mean	77	18.83	0.6833	117	74.33	69.17	31.33	16.45
Std. Deviation	6.066	2.317	0.1722	4.942	5.888	3.545	5.007	2.971
Std. Error	2.477	0.9458	0.07032	2.018	2.404	1.447	2.044	1.213
GROUP II	**Blood sugar (mg/dl)**	**BUN (mg/dl)**	**Serum creatinine (mg/dl)**	**Serum total cholesterol (mg/dl)**	**Serum triglycerides level (mg/dl)**	**Serum HDL cholesterol (mg/dl)**	**Serum LDL cholesterol (mg/dl)**	**Serum VLDL cholesterol (mg/dl)**
Mean	78.83	15.33	0.85	124.3	78.83	67.33	38	18.93
Std. Deviation	6.676	4.967	0.2258	11.01	10.38	5.279	9.899	1.484
Std. Error	2.725	2.028	0.0922	4.495	4.238	2.155	4.041	0.6059
GROUP III	**Blood sugar (mg/dl)**	**BUN (mg/dl)**	**Serum creatinine (mg/dl)**	**Serum total cholesterol (mg/dl)**	**Serum triglycerides level (mg/dl)**	**Serum HDL cholesterol (mg/dl)**	**Serum LDL cholesterol (mg/dl)**	**Serum VLDL cholesterol (mg/dl)**
Mean	84.83	16.83	0.8	113.8	87.33	67.33	30.83	15.62
Std. Deviation	13.09	3.125	0.1789	8.477	16.08	5.046	6.911	3.421
Std. Error	5.344	1.276	0.07303	3.461	6.566	2.06	2.822	1.397

Values are mean ± S.D (n = 6 per group of which 3 males and 3 females). Control and treatment groups were compared statistically using one way ANOVA followed by Dunnett's test.

Effect of *Oma Legium* on Serum Bio-chemistry profile of rats in sub-acute toxicity study

GROUP I	**Serum total protein (g/dl)**	**Serum albumin (g/dl)**	**(AST) (IU/ml)**	**(ALT) (IU/L)**	**(ALP) (IU/L)**
Mean	6.35	3.6	102.3	36.5	112
Std. Deviation	0.9995	0.08944	13.87	7.714	15.47
Std. Error	0.408	0.03651	5.661	3.149	6.314
GROUP II	**Serum total protein (g/dl)**	**Serum albumin (g/dl)**	**(AST) (IU/ml)**	**(ALT) (IU/L)**	**(ALP) (IU/L)**
Mean	5.767	3.933	109.5	22.17	137.8
Std. Deviation	0.8914	0.5354	19.65	2.927	13.33
Std. Error	0.3639	0.2186	8.024	1.195	5.443
GROUP III	**Serum total protein (g/dl)**	**Serum albumin (g/dl)**	**(AST) (IU/ml)**	**(ALT) (IU/L)**	**(ALP) (IU/L)**
Mean	6.233	4.083	99.33	27.83	114.7
Std. Deviation	0.9158	0.6646	10.21	4.875	26.47
Std. Error	0.3739	0.2713	4.169	1.99	10.81

Values are mean ± S.D (n = 6 per group of which 3 males and 3 females). Control and treatment groups were compared statistically using one way ANOVA followed by Dunnett's test.

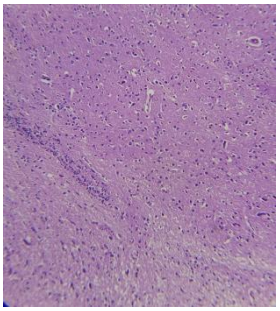
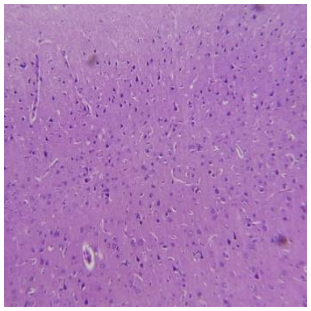
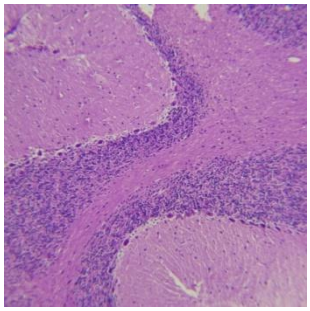
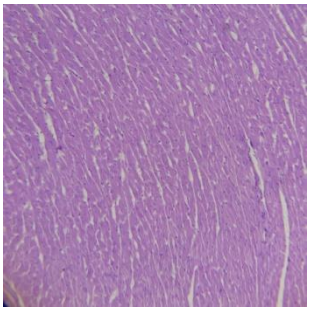
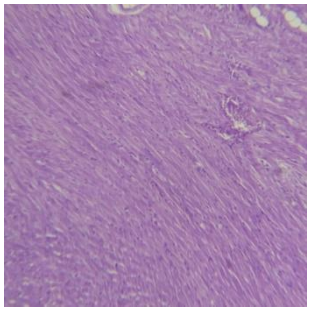
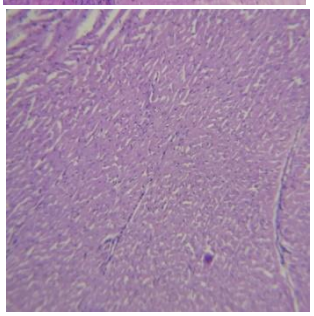
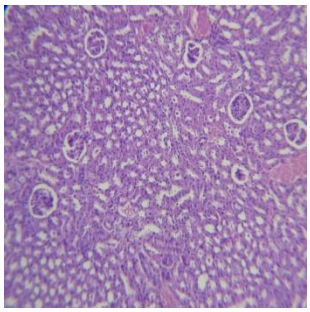
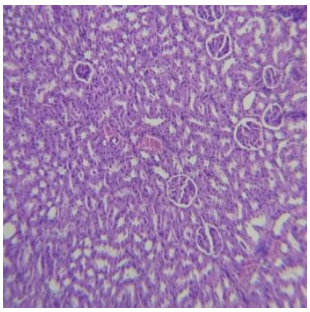
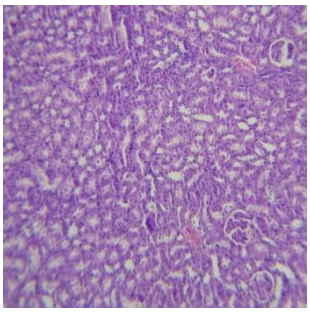
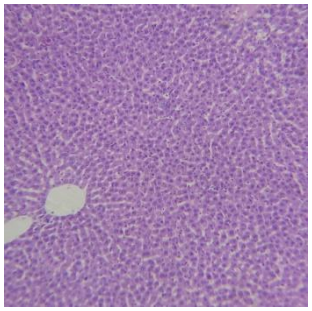
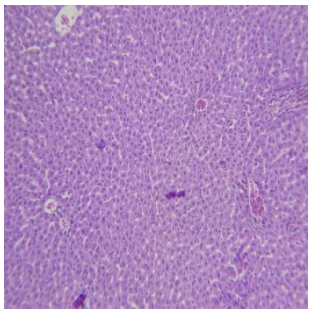
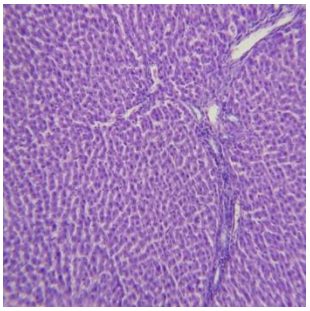
Quantitative data on absolute organ weight of rats treated with *Oma Legium* for 28 days in Sub-acute toxicity study.

GROUP I	**HEART (gms)**	**LIVER (gms)**	**KIDNEYS (gms)**	**SPLEEN (gms)**	**BRAIN (gms)**	**LUNG (gms)**	**STOMACH (gms)**	**TESTES (gms)**	**UTERUS & OVARY (gms)**
Mean	0.7683	5.948	1.617	0.5667	1.483	1.6	1.15	1.833	0.8667
Std. Deviation	0.05636	0.9834	0.2137	0.1633	0.1472	0.3162	0.501	0.4933	0.4041
Std. Error	0.02301	0.4015	0.08724	0.06667	0.06009	0.1291	0.2045	0.2848	0.2333
GROUP II	**HEART (gms)**	**LIVER (gms)**	**KIDNEYS (gms)**	**SPLEEN (gms)**	**BRAIN (gms)**	**LUNG (gms)**	**STOMACH (gms)**	**TESTES (gms)**	**UTERUS & OVARY (gms)**
Mean	0.6517	5.103	1.667	0.6333	1.7	1.583	1.083	2.633	0.7333
Std. Deviation	0.2142	0.669	0.1966	0.1506	0.2098	0.2994	0.4622	1.007	0.4933
Std. Error	0.08746	0.2731	0.08028	0.06146	0.08563	0.1222	0.1887	0.5812	0.2848
GROUP III	**HEART (gms)**	**LIVER (gms)**	**KIDNEYS (gms)**	**SPLEEN (gms)**	**BRAIN (gms)**	**LUNG (gms)**	**STOMACH (gms)**	**TESTES (gms)**	**UTERUS & OVARY (gms)**
Mean	0.755	5.862	1.733	0.6	1.533	1.55	1.033	3.167	0.8667
Std. Deviation	0.1748	0.6814	0.1033	0.1549	0.1366	0.2168	0.2875	0.6658	0.3786
Std. Error	0.07136	0.2782	0.04216	0.06325	0.05578	0.08851	0.1174	0.3844	0.2186

Values are mean ± S.D (n = 6 per group of which 3 males and 3 females) for Heart, Liver, Kidney, Brain, Spleen, Lung, Stomach. Values are mean ± S.D (n = 3 per group per sex) for testes , ovary and uterus for Control and treatment groups were compared statistically using one way ANOVA followed by Dunnett's test.

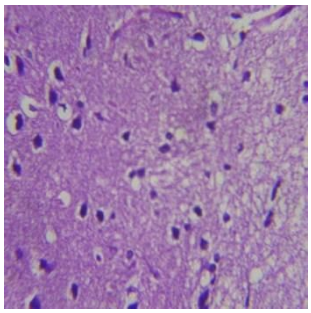
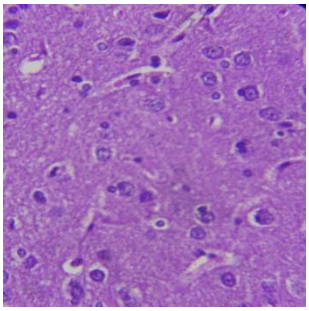
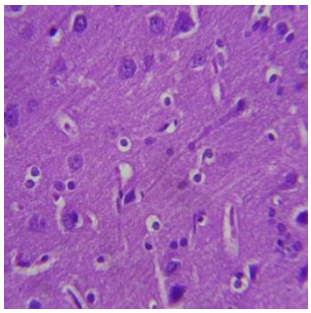
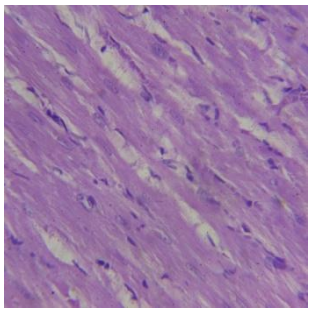
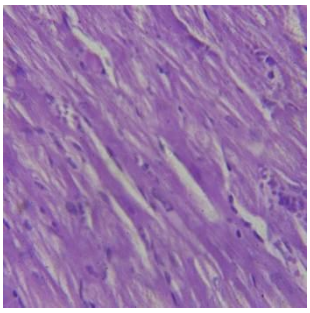
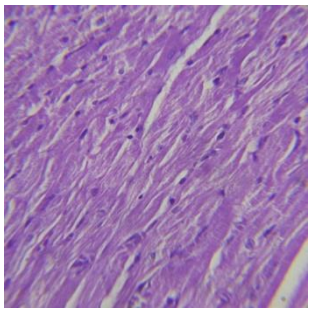
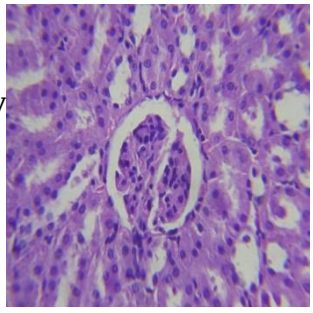
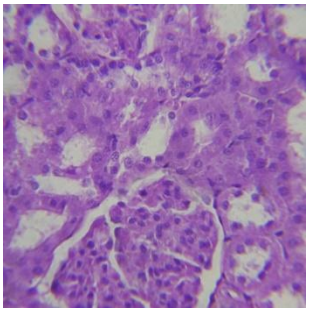
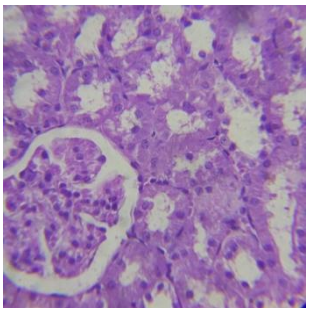
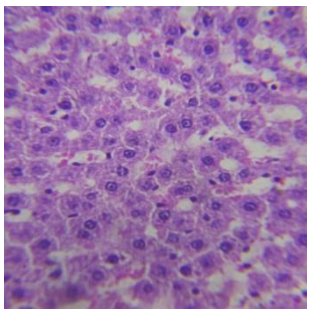
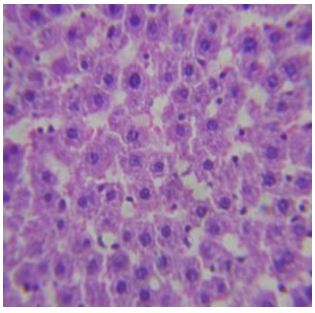
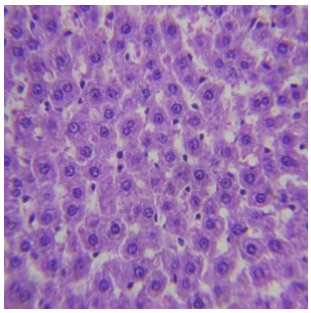
Histopathological analysis (Female Rat) in Sub-acute toxicity Study

Low Power Magnification 10X

	Group I	Group II	Group III
Brain			
Heart			
Kidney			
Liver			

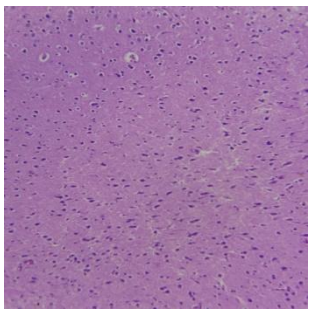
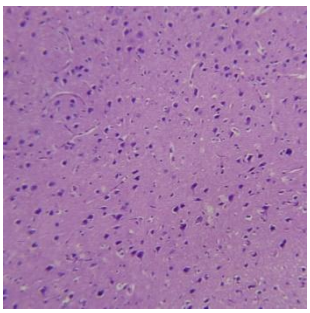
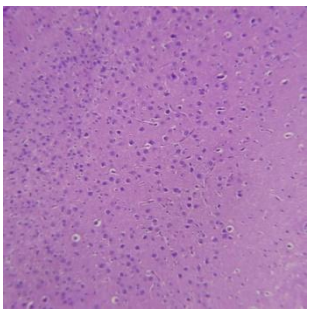
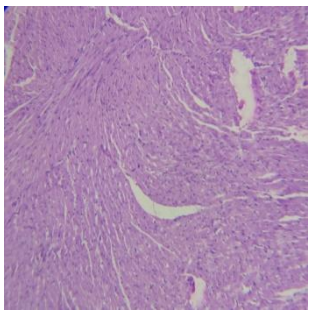
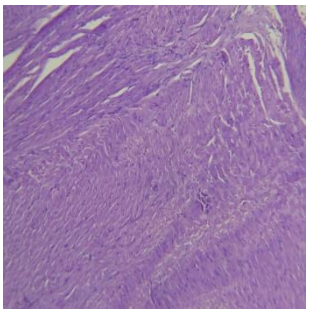
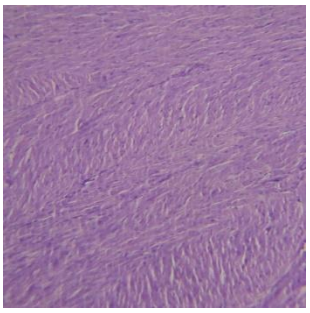
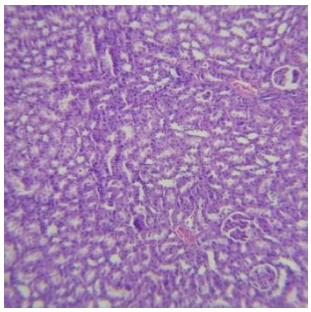
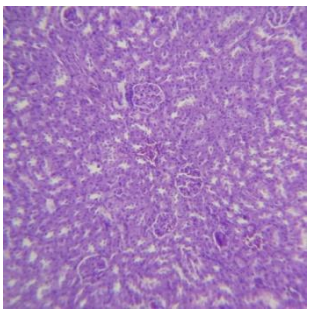
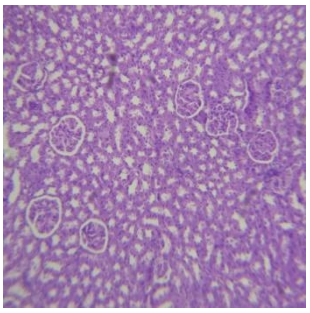
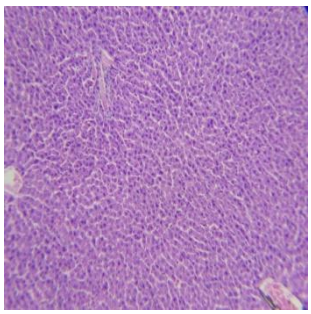
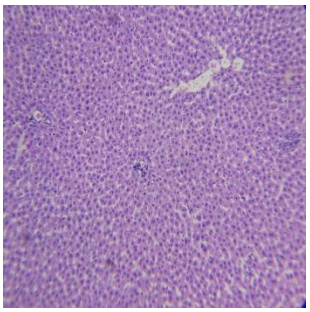
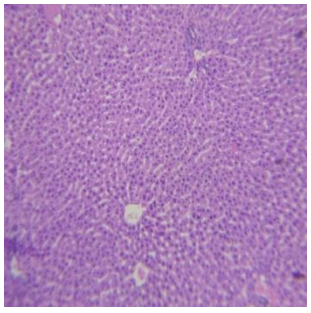
Histopathological analysis (Female Rat) in Sub-acute toxicity Study

High Power Magnification 40X

	Group I	Group II	Group III
Brain			
Heart			
Kidney			
Liver			

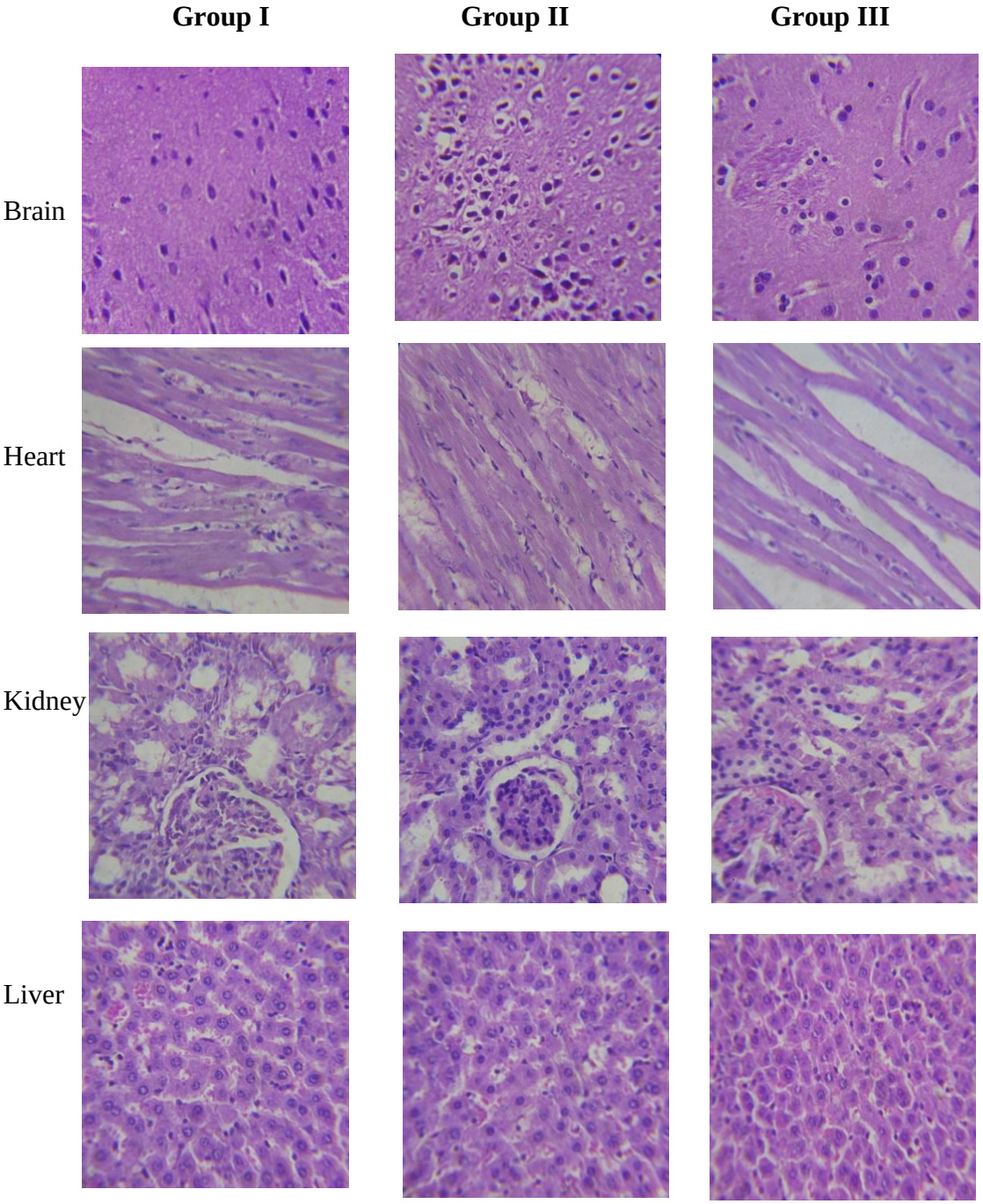
Histopathological analysis (Male Rat) in Sub-acute toxicity Study

Low Power Magnification 10X

	Group I	Group II	Group III
Brain			
Heart			
Kidney			
Liver			

Histopathological analysis (Male Rat) in Sub-acute toxicity Study

High Power Magnification 40X



HISTOPATHOLOGY REPORT

BRAIN

Appearance of inter neuronal space and count appears normal with regular morphology of brain parenchymal cells. No signs of degeneration and hemorrhage were observed in sample belongs to group I,II and III.

HEART

Myocardial fiber mass appears denser with no signs of degeneration or fibrosis were observed in samples belongs to group I, II and III.

LUNG

Light microscopic examination of lung revealed normal alveoli and alveolar sac with no signs of infiltration in both control and treated rats.

STOMACH

Light microscopic observation stomach reveals normal histology of gastric wall composed of normal mucosa, muscularismucosa, submucosa, muscularispropiria and adventitia. No signs of ulceration were observed in sample belongs to group I, II and III.

LIVER

Cytoplasm appears normal with widen portal tract. Hepatocellular architecture was normal with no signs of necrosis .A considerable number of Kupffer cells are observed in the sinusoid walls were observed in in sample belongs to group I, II and III.

SPLEEN

Appearance of central artery and marginal sinus are normal . Lymphoid follicles appears normal . Marginal sinus (MS) of the rat and its sinus lining cells appears normal. Erythropoietic cells (EP) are scattered throughout the red pulp of sample belongs to group I, II and III.

KIDNEY

Lumen of vessels and bowman's space appears normal. Glomerular basement membrane appears normal. Epithelial lining on proximal convoluted tubule appears normal in sample belongs to group I,II and III.

TESTES

Presence of mature somatic cells project the perfect histomorphology of testicular cells in this group. Primary spermatocytes with large centered nucleus and dense chromatin were observed in sample belongs to group I,II and III.

UTERUS

Appearance of endometrium, myometrium and uterine glands was normal. Arrangement of stratum basale, functionale and surface epithelium seems normal in samples belongs to group I,II and III.

OVARY

Histopathological analysis of ovary showing normal corpus luteum (CL) and Primordial follicles with few mature ovarian follicles with no signs of abnormality. Appearance of antral follicle, primary oocyte and secondary follicles are normal in sample belong to group I,II and III.

Molecular Docking Study Report

Name of the Client: Dr. Sumathi

Purpose: Computational Analysis

Project ID : NRS/AS/0019/01/2017

Formulation : Oma Legium

Indication : **Scabies/ Immuno Modulatory/ Anti Allergic**

Source: Trachyspermum Ammi

Phyto Components	**Action**	**Reference**
Beta pinene	Anti-Microbial	https://www.ncbi.nlm.nih.gov/pubmed/22634841
	Anti-scabies	http://www.rjpbcs.com/pdf/2014_5(3)/[154].pdf
Thymol	Anti-Bacterial	https://www.ncbi.nlm.nih.gov/pubmed/7938073
	Antioxidant	https://core.ac.uk/download/pdf/11978224.pdf
	Mast cell inhibitor-Immunomodulatory	https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4040322/
	Anti-allergic and anti-inflammatory	http://pubs.sciepub.com/ajmbr/1/4/4/
	Anti-Fungal	https://bmccomplementalternmed.biomedcentral.com/articles/10.1186/s12906-015-0947-2
	Anti-scabies	http://www.rjpbcs.com/pdf/2014_5(3)/[154].pdf
Carvacrol	Anti-Microbial	http://www.microbiologyresearch.org/docserver/fulltext/jmm/56/4/519.pdf?expires=1494922941&id=id&accname=guest&checksum=1310A657AC3DC34560A298784FF27E42
	Anti-allergic and anti-inflammatory	http://online.liebertpub.com/doi/abs/10.1089/jmf.2012.0102
	Anti-scabies	http://www.rjpbcs.com/pdf/2014_5(3)/[154].pdf

Compounds / Drug Selected for Docking based on literature

- Beta pinene
- Carvacrol
- Thymol

Receptors / Target protein Selected for Docking

Name of the Protein	PDB code	Standard antagonist
Histamine 1 receptor	3RZE	Cetirizine
Prostaglandin H2 synthases	1igx	Salycilic acid
Cyclooxygenase I	3KK6	Ibuprofen
Cyclooxygenase 2	6COX	Celecoxib

Methodology

Docking calculations were carried out using Auto Dock 4. Gasteiger partial charges were added to the ligand atoms. Non-polar hydrogen atoms were merged, and rotatable bonds were defined. Docking calculations were carried out for test drug ***Beta pinene, Carvacrol, Thymol and standard Cetirizine, Salycilic acid, Ibuprofen and Celecoxib against target protein*** protein model. Essential hydrogen atoms, Kollman united atom type charges, and solvation parameters were added with the aid of AutoDock tools (*Morris, Goodsell et al., 1998*). Affinity (grid) maps of ×× Å grid points and 0.375 Å spacing were generated using the Autogrid program (*Morris, Goodsell et al., 1998*). AutoDock parameter set- and distance-dependent dielectric functions were used in the calculation of the van der Waals and the electrostatic terms, respectively. Docking simulations were performed using the Lamarckian genetic algorithm (LGA) and the Solis & Wets local search method (*Solis and Wets, 1981*). Initial position, orientation, and torsions of the ligand molecules were set randomly. All rotatable torsions were released during docking. Each docking experiment was derived from 2 different runs that were set to terminate after a maximum of 250000 energy evaluations. The population size was set to 150. During the search, a translational step of 0.2 Å, and quaternion and torsion steps of 5 were applied.

Final Docking result Analysis
Cyclooxygenase 1 Receptor

Rank	interaction	Compound	Amino Acid Sequence									
	10	**Ibuprofen**	205 PHE	209 PHE	348 TYR	352 LEU	381 PHE	385 TYR	387 TRP	518 PHE	530 SER	534 LEU
1	**6**	**Beta Pinene**	352 LEU	381 PHE	384 LEU	385 TYR	387 TRP	518 PHE	530 SER			
2	**4**	**Carvacrol**	349 VAL	384 LEU	385 TYR	387 TRP	518 PHE	523 ILE	527 ALA	530 SER	531LEU	
0	**0**	**Thymol**	No Interaction									

Out of three compound's Betapinene has 6 interactions (60%) similar to that of the standard Ibuprofen hence it has promising COX 1 inhibition activity similarly other compound Carvacrol has 40% percentage similar interaction to that of the standard hence both compounds has COX 1 inhibition activity. Compound Thymol has no COX1 inhibition activity.

Cyclooxygenase 2 Receptor

Rank	Amino Acid interaction	Compound	Amino Acid Sequence				
	5	Celecoxib	54 GLN	55 TYR	56 LYS	57 CYS	67 GLU
1	3	Betapinene	55 TYR	56 LYS	67 GLU		
1	3	Carvacrol	54 GLN	55TYR	67GLU		
2	1	Thymol	35 PRO	37 CYS	38 SER	55 TYR	165 VAL

Out of three compound's Betapinene and Carvacrol has 3 interactions (60%) similar to that of the standard Celecoxib hence it has promising COX 2 inhibition activity similarly other compound Thymol has 20% percentage similar interaction to that of the standard hence all three compounds has promising COX 2 inhibition activity.

Histamine 1 Receptor

Rank	Amino Acid interaction	Compound	Amino Acid Sequence														
	15	Citrazine	84 ASN	103 TRP	107 ASP	108 TYR	111 SER	158 TRP	179 LYS	194 THR	424 PHE	428 TRP	431 TYR	432 PHE	435 PHE	454 ILE	458 TYR
3	4	Betapinene	108 TYR	111 SER	112 THR	115 ILE	198 ASN	424 PHE	432 PHE								
1	8	Carvacrol	107 ASP	108 TYR	111 SER	115 ILE	158 TRP	198 ASN	199 PHE	424 PHE	428 TRP	431 TYR	432 PHE				
2	7	Thymol	107 ASP	108 TYR	111 SER	112 THR	115 ILE	199 PHE	424 PHE	428 TRP	431 TYR	432 PHE					

Out of three compound's Carvacrol has 8 interactions (53%) similar to that of the standard Citrazine hence it has Histamine 1 Receptor inhibition activity similarly other two compounds thymol has 46% percentage and Betapinene has 26% similar interaction to that of the standard hence all three compounds has promising Histamine 1 receptor inhibition activity.

Prostaglandin Synthase

Rank	Amino Acid interaction	Compound	Amino Acid Sequence				
	5	Salicylic acid	35 PRO	38 TYR	40 PRO	54 ARG	55 TYR
3	1	Betapinene	55 TYR	67 PRO	68 ASN		
1	4	Carvacrol	35 PRO	38 TYR	40 PRO	55 TYR	
2	2	Thymol	54 ARG	55 TYR	67 PRO	68 ASN	

Out of three compound's Carvacrol has 4 interactions (90%) similar to that of the standard Citrazine Salicylic acid hence it has Prostaglandin Synthase inhibition activity similarly other two compounds thymol has 40% percentage and Betapinene has 20% similar interaction to that of the standard hence all three compounds has promising Prostaglandin Synthase inhibition activity.

Conclusion

Based on the results of the computational analysis it was concluded that the compound's such as Betapinene, Thymol , Carvacrol present in the formulation Oma Legium possess significant inhibition of COX 1& 2 ,Prostaglandin synthases and Histamine 1blocking activity there it was concluded that this formulation may have promising anti-inflammatory, anti-allergic, immune modulatory activity

Purpose: Anti- Microbial Profiling

Project Id: NRS/AS/0019/01/2017

Total Sample: 01

Sample ID: OL

Institute: Govt Siddha Medical College, Chennai

Disc-diffusion method:

The antibacterial activities of the sample OL were carried out by disc diffusion method. The concentrations of the test compounds were used at the concentration of 100, 200, 300 µg. The target microorganisms were cultured in Mueller–Hinton broth (MHB). After 24 h the suspensions were adjusted to standard sub culture dilution. The Petri dishes containing Muller Hinton Agar (MHA) medium were cultured with diluted bacterial strain. Disc made of Whatman No.1, diameter 6 mm was pre-sterilized and was maintained in aseptic chamber. Each concentration was injected to the sterile disc papers. Then the prepared discs were placed on the culture medium. Standard drug Ciprofloxacin (5µg) for anti-bacterial and Fluconazole (25µg) was used as a positive reference standard to determine the sensitivity of each microbial species tested. Then the inoculated plates were incubated at 37^{o} C for 24 h (Bacterial) - 72 hr (Fungal). The diameter of the clear zone around the disc was measured and expressed in millimeters as its anti-microbial property. The results were depicted in **Table.**

Organisms used for Anti-Bacterial Activity

s.no	organisms	Type
1.	***Staphylococcus aureus***	**Gram-positive**
2.	***Streptococcus pyogenes***	**Gram-positive**

Organisms used for Anti-Fungal Activity

s.no	organisms
1.	***Candida albicans***
2.	***Aspergillus niger***

Zone of Inhibition data of Anti-Microbia activity

Sample Code	Streptococcus pyogenes			Staphylococcus aureus			Candida albicans			Aspergillus niger		
Concentraion	100 µg	200 µg	300 µg	100 µg	200 µg	300 µg	100 µg	200 µg	300 µg	100 µg	200 µg	300 µg
OL	2	4	9	-	-	-	-	-	-	-	-	-
Ciprofloxacin (5µg)	25			26			NA			NA		
Fluconazole (25µg)	NA			NA			19			16		

- = Not active

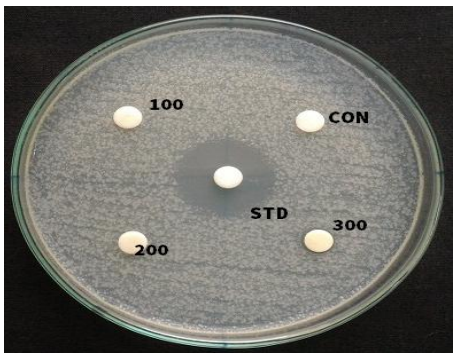
NA = Not Applicable

Conclusion

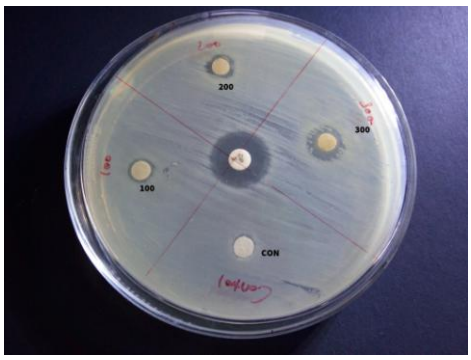
From the results of the present study it was concluded that the sample OL was effective against ***Streptococcus pyogenes*** and not active against ***Staphylococcus aureus Candida albican and Aspergillus niger.***

Anti-Bacterial Evaluation of OL

Anti- Microbial Effect of OL against ***Staphylococcus aureus***

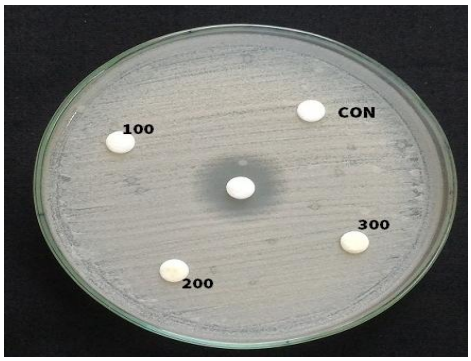


Anti- Microbial Effect of OL against ***Streptococcus pyogenes***

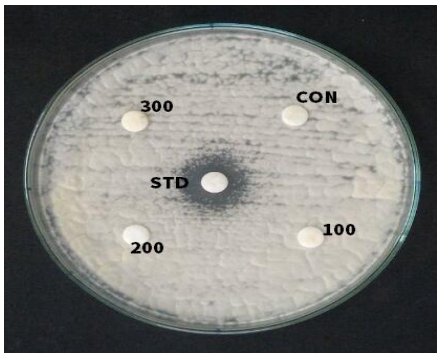


ANTI-FUNGAL EVALUATION

Anti- Microbial Effect of OL against ***Candida albicans***



Anti- Microbial Effect of OL against ***Aspergillus niger***



BIO – STATISTICS

Treatment for sirangu(Scabies):

The most popular non parametric statistical tool, namely, McNemar Test analysis has been employed to analyses the effectiveness with the help of a hypothesis.

S.NO	Clinical Features	Before Treatment	After Treatment
		n%	n%
1.	Nocturnal Itching	40(100)	3(7.5)**
2.	Burrow	4(100)	2(5)**
3.	Pruritic Papules	30(75)	3(7.5)**
4.	Pustules	27(67.5)	0(0)**
5.	Papulo Vesicules	17(42.5)	0(0)**

Mc Nemat test, C.I:95%, * P<0.05; ** P<0.01

Software: spss17version

Number of cases: 40

Inference:

Since the p value is significant in all clinical features. So there is significant reducing of clinical features among the patients for the treatment of sirangu(Scabies). Hence it is concluded that the treatment was effective and significant.

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CHENNAI – 600 106

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CLINICAL STUDY ON **"OMA LEGIUM & MUSUTTAI ENNAI"** IN THE TREATMENT **"SIRANGU'' (SCABIES IN CHILDREN).**

FORM l - SCREENING AND SELECTION PROFORMA

1. OP NO:

2. NAME:

3. AGE: **4.GENDER**

5. F.OCCUPATION **6. F.INCOME:**

7. ADDRESS:

8. CONTACT NO:

INCLUSION CRITERIA:

Age: 3-7 Yrs.	Yes/No
Nocturnal itching.	Yes/No
Pruritic papules	Yes/No
Burrow	Yes/No
Pustules	Yes/No
Papulo vesicles	Yes/No

Lesion seen in

Web of hand	Yes/No
Wrist	Yes/No
Ulnar aspect of forearm.	Yes/No

Elbow	Yes/No
Axillae	Yes/No
Feet	Yes/No
Buttock	Yes/No
Palms	Yes/No
Genital area	Yes/No
Sole	Yes/No

Patients who are willing to undergo Laboratory investigation.

Yes / No

Patients who are willing to sign the informed consent stating that she will conscientiously stick to the treatment during 21 days but can opt out of the trial of her own conscious discretion. Yes / No

EXCLUSION CRITERIA

ADMITTED TO TRIAL:

YES NO

If YES, OPD/IPD

Date:

Station:

Signature of the Guide **Signature of the Investigator**

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FORM lI -HISTORY TAKING PROFORMA

1. SERIAL NO OF THE CASE: ……. 2.OP NO: ..... 3. NAME: …… 4. AGE: ……..

5. GENDER: ……..

5. F. OCCUPATION: ……

6.F. INCOME: ……..

7. COMPLAINTS & DURATION:

8. PERSONAL HISTORY:

9. HISTORY OF PREVIOUS ILLNESS:

10. BIRTH HISTORY:

11. DIETARY HABIT:

1. Vegetarian
2. Non-vegetarian

12. FAMILY HISTORY:

Whether this problem runs in family?

1. Yes 2.No

If yes, mention the relationship of affected person(s) ----------

History of previous investigations if any ----------

Signature of the Guide **Signature of the Investigator**

Date:

Station:

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CLINICAL STUDY ON **"OMA LEGIUM & MUSUTTAI ENNAI"** IN THE TREATMENT **"SIRANGU'' (SCABIES IN CHILDREN)**

FORM III ASSESSMENT PROFORMA

1. SERIAL NO: ……

2. OP NO: .....

3. NAME: …… 4.AGE: …… 5.GENDER: .....

GENERAL EXAMINATION:

Height (cms)	**: …….**
Weight (kg)	**: …….**
Temperature (°F)	**: …….**
Pulse rate (/min)	**: …….**
Heart rate (/min)	**: …….**
Respiratory rate (/min)	**: …….**
Blood pressure (mm/Hg)	**: …….**

	Present	**Absent**
Pallor		
Jaundice		
Cyanosis		
Lymphadenopathy		
Pedal edema		
Clubbing		
Jugular vein pulsation		

SYSTEMIC EXAMINATION

Cardio Vascular System	**: …….**
Respiratory system	**: …….**
Gastro-intestinal system	**: …….**
Central Nervous System	**: …….**

Urogenital system : …….

Endocrine System : …….

SIDDHA SYSTEM OF EXAMINATIONS:

1. THEGI: [BODY CONSTITUTION]

1. Vatha udal
2. Pitha udal
3. Kaba udal
4. Thontha udal

2. NILAM: [LAND WHERE PATIENT LIVED MOST]

1. Kurinji (Hilly terrain)
2. Mullai (Forest range)
3. Marutham (Plains)
4. Neithal (Coastal belt)
5. Paalai (Arid regions)

3. KAALAM:

1. Kaar kaalam
2. Koothir kaalam
3. Munpani kaalam
4. Pinpani kaalam
5. Ilavenil kaalam
6. Muthuvenil kaalam

4. GUNAM:

1. Sathuvam
2. Raasatham
3. Thaamatham

5. IMPORIGAL (SENSORY ORGANS):

Normal/Affected

Mei ----------

Vaai ----------

Kann ----------

Mukku ----------

Sevi ----------

6. KANMENDHIRIYAM (MOTOR ORGANS):

Kai ----------

Kal ----------

Vaai ----------

Eruvai ----------

Karuvaai ----------

7. KOSANGAL (SHEATH):

Annamaya kosam ----------

Pranamaya kosam ----------

Manomaya kosam ----------

Vignana maya kosam ----------

Anandamaya kosam ----------

8. UYIR THAATHUKKAL: **[THREE HUMORS] (VALI, AZHAL, IYAM)**

A) VALI

Pranan –----------

Abanan ----------

Samanan ----------

Uthanan ----------

Vyanan ----------

Naagan ----------

Koorman ----------

Kirukaran----------

Devathathan ----------

Dhananjayan ----------

B) AZHAL

Analakam ----------

Ranjakam ----------

Sathakam ----------

Prasakam ----------

Alosakam ----------

C) IYAM

Avalambagam ----------

Kilethagam ----------

Pothagam ----------

Tharpagam ----------

Santhigam ----------

9. SEVEN UDAL THATHUKKAL: (SEVEN SOMATIC COMPONENTS)

Saram ----------

Senneer ----------

Oon ----------

Koluppu ----------

Enbu ----------

Moolai ----------

Sronitham ----------

10. ENVAGAI THERVU:

I. NAADI: [PULSE PERCEPTION]

II. SPARISAM: [PALPATION}

III. NAA: [TONGUE]

IV.NIRAM: [COMPLEXION]

1. Vatham
2. Pitham
3. Kabam

V.MOZHI: [VOICE]

1. High Pitched
2. Low Pitched
3. Medium Pitched

VI.VIZHI: [EYES]

VII. MALAM: [BOWEL HABITS / STOOLS]

Niram

Irugal

Ilagal

Others

VIII. MOOTHIRAM [URINE EXAMINATION]

NEERKKURI:

Niram

Manam

Edai

Nurai

Enjal

NEIKKURI

Signature of the Guide **Signature of the Investigator**

Date:

Station:

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CLINICAL STUDY ON **"OMA LEGIUM & MUSUTTAI ENNAI"** IN THE TREATMENT OF **" SIRANGU'' (SCABIES IN CHILDREN)**

FORM IV: LABORATORY INVESTIGATIONS PROFORMA

1. SERIAL NO OF THE CASE: ……

2. OP NO: .....

3. NAME: …… 4.AGE: …… 5.GENDER: .....

A) BLOOD INVESTIGATIONS:

BLOOD INVESTIGATIONS		**BEFORE TREATMENT**	**AFTER TREATMENT**
Hb (gm/dL)			
ESR (mm)	**½ hr.**		
	1 hr.		
T.WBC (Cells / Cu.mm)			
Differential Count (%)	**Polymorphs**		
	Lymphocytes		
	Monocytes		
	Eosinophils		
	Basophils		

B) URINE INVESTIGATIONS:

URINE INVESTIGATIONS	**BEFORE TREATMENT**	**AFTER TREATMENT**
Albumin		
Sugar		
Deposits		

Signature of the Guide **Signature of the Investigator**

Date:

Station:

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FORM V: INFORMED CONSENT FORM

"I have read the foregoing information, or it has been read to me. I have had the opportunity to ask questions about it and any questions I have asked have been answered to my satisfaction.

I consent voluntarily to participate my child in this study and understand that I have the right to withdraw from the study at any time without in any way it affecting my child further medical care*".*

"I have received a copy of the information sheet/consent form".

Date:

Signature of the participant:

In case of illiterate participant

"I have witnessed the accurate reading of the consent form to the potential participant, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely*."*

Date:

Signature of a witness Left thumb Impression of the Participant

(Selected by the participant bearing no connection with the survey team)

Date:

Station:

Signature of participant:

Signature of the Guide: **Signature of the Investigator:**

அரசு சித்த மருத்துவக் கல்லூரி, சென்னை-106
அறிஞர் அண்ணா மருத்துவமனை, சென்னை
சிரங்கு நோய்க்கான சித்த மருந்தின் **(ஓம லேகியம் & முசுட்டை எண்ணெய்)**

பரிகரிப்புத் திறனைக் கண்டறியும் மருத்துவ ஆய்விற்கான தகவல் படிவம்

ஒப்புதல் படிவம் ஆய்வாளரால் சான்றளிக்கப்பட்டது.

நான் இந்த ஆய்வை குறித்த அனைத்து விபரங்களையும் நோயாளிக்கு புரியும் வகையில் எடுத்துரைத்தேன் என உறுதியளிக்கிறேன்.

தேதி: கையொப்பம்:

இடம்: பெயர்:

நோயாளியின் பெற்றோர் ஒப்புதல் படிவம்

என்னிடம் இந்த மருத்துவ ஆய்வின் காரணத்தையும், மருந்தின் தன்மை மற்றும் மருத்துவ வழிமுறை பற்றியும், தொடர்ந்து எனது உடல் இயக்கத்தை கண்காணிக்கவும், அதனை பாதுகாக்கவும் பயன்படும் மருத்துவ ஆய்வுக்கூட பரிசோதனைகள் பற்றி திருப்தி அளிக்கும் வகையில் ஆய்வு மருத்துவரால் விளக்கிக் கூறப்பட்டது.

நான் எனது குழ்ந்தையின் இந்த மருத்துவ ஆய்வின் போது காரணம் எதுவும் கூறாமல், எப்பொழுது வேண்டுமானாலும் இந்த ஆய்விலிருந்து எனது குழந்தையை விடுவித்து கொள்ளும் உரிமையை தெரிந்திருக்கின்றேன். நான் என்னுடைய சுதந்திரமாக தேர்வு செய்யும் உரிமையைக் கொண்டு நோய்க்கான மருந்தின் பரிகரிப்பும் **(ஓம லேகியம் & முசுட்டை எண்ணெய்)** திறனைக் கண்டறியும் மருத்துவ ஆய்விற்கு என்னை உட்படுத்த ஒப்புதல் அளிக்கிறேன்.

தேதி: கையொப்பம்:

இடம்: பெயர்:

தேதி: சாட்சிக்காரர் கையொப்பம்:

இடம்: பெயர்:

உறவுமுறை:

துறைத்தலைவர் கையொப்பம்: ஆராய்ச்சியாளர் கையொப்பம்:

GOVERNMENT SIDDHA MEDICAL COLLEGE

ARIGNAR ANNA GOVERNMENT HOSPITAL OF INDIAN MEDICINE

CHENNAI – 600 106

POST- GRADUATE DEPARTMENT OF KUZHANTHAI MARUTHUVAM

CLINICAL STUDY ON **"OMA LEGIUM & MUSUTTAI ENNAI"** IN THE TREATMENT OF **"SIRANGU'' (SCABIES IN CHILDREN)**

FORM VI - WITHDRAWAL FORM

SI NO:

OP NO:

NAME:

AGE / GENDER:

DATE OF TRIAL COMMENCEMENT:

DATE OF WITHDRAWAL FROM TRIAL:

REASONS FOR WITHDRAWAL:

- Long absence at reporting : Yes/ No
- Irregular treatment: Yes/ No
- Shift of locality : Yes/No
- Increase in severity of symptoms: Yes/No
- Development of severe adverse drug reactions: Yes/No

Signature of the Guide **Signature of the Investigator**

Date:

Station:

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CLINICAL STUDY ON **““OMA LEGIUM & MUSUTTAI ENNAI”** IN THE TREATMENT OF **“SIRANGU’’ (SCABIES IN CHILDREN)**

FORM VII – PATIENT INFORMATION SHEET

Name of Co- Investigator: Sumathi.M **Name of the college:** Govt.Siddha. Medical College

Arumbakkam

Chennai-106.

INFORMATION SHEET FOR PATIENTS PARTICIPATING IN THE OPEN CLINICAL TRIAL.

I M.Sumathi studying M.D (Siddha) at Govt.Siddha Medical College, Chennai, is doing a clinical trial on ‘‘Sirangu -Scabies in children. It is becoming a most common disease, occurring throughout the world. In this regard, I am in need to ask you few questions. I will maintain confidentiality of your comments and data obtained. There will be no risk of disclosing your identity and no physical, psychological or professional risk is involved by taking part in this study. Taking part in this study is voluntary. No compensation will be paid to you for taking part in this study.

You can choose not to take part. You can choose not to answer a specific question. There is no specific benefit for you if you take part in the study. However, taking part in the study may be of benefit to the community, as it may help us to understand the problem of defaulters and potential solutions.

If you agree to be a participant in this study, you will be included in the study primarily by signing the consent form and then you will be given the internal medicine **“OMA LEGIUM”** (Internal medicine) 5gm /twise a day **“MUSUTTAI ENNAI”** (External medicine) for 21 days.

The information I am collecting in this study will remain between you and the Co-investigator (myself). I will ask you few questions through a questionnaire. I will not write your name on this form. I will use a code instead.The questionnaire will take approximately 20 minutes of your time.

If you wish to find out more about this study before taking part, you can ask me all the questions you want or contact M.Sumathi, PG Scholar cum Co- investigator of this study, attached to Govt. Siddha Medical College, Chennai-106. You can also contact the Member-secretary of Ethics committee, Govt.Siddha Medical College, Chennai.

அரசு சித்த மருத்துவக் கல்லூரி, சென்னை-106

அறிஞர் அண்ணா மருத்துவமனை, சென்னை

சிரங்கு நோய்க்கான சித்த மருந்தின் **(ஓம லேகியம் & முசுட்டை எண்ணெய்)** பரிகரிப்புத் திறனைக் கண்டறியும் மருத்துவ ஆய்விற்கான தகவல் படிவம்

ஆராய்ச்சியாளர் பெயர்: மா சுமதி

நிறுவனத்தின் பெயர்:அரசு சித்த மருத்துவக் கல்லூரி

அரும்பாக்கம், சென்னை-106

அரசு சித்த மருத்துவக் கல்லூரியில் பட்டமேற்படிப்பு பயின்று வரும் நான் மருத்துவர் கோ.ஞா.கலைச்செல்வி **சிரங்கு** என்னும் நோயில் மருத்துவ ஆராய்ச்சியில் ஈடுபட்டுள்ளேன்.

இந்த நோய் கிருமிகளினால் ஏற்படுகின்றன. இது பரவக் கூடிய நோய்.

இந்த ஆராய்ச்சி சம்பந்தமாக சில கேள்விகளைக் கேட்கவும், தேவையான ஆய்வகப் பரிசோதனைக்கு தங்கள் குழந்தையை உட்படுத்தவும உள்ளேன்.

இந்த ஆராய்ச்சிக்கு தங்கள் விருப்பத்தின் பேரில் உட்படும் பட்சத்தில் உள்மருந்நாக **ஓம லேகியம்** 5gm/twise a day, வெளிமருந்தாக **முசுட்டை எண்ணெய்** பயன்படுகின்றது.

இந்த மருந்து சிறப்பாக **சிரங்கு** நோய்க்காக அங்கீகரிக்கப்பட்ட சித்த மருத்துவ நூலில் கூறப்பட்டுள்ளது

இந்த ஆராய்ச்சியில் தங்களை அனுமதித்த பிறகு உங்களுக்கு விருப்பம் இல்லையெனில் எப்போது வேண்டுமானாலும் ஆராய்ச்சியில் இருந்து விலகிக் கொள்ள உரிமை உள்ளது.

இந்த ஆராய்ச்சிக்கு சம்பந்தமாக நோயின் தன்மை பற்றியும் மற்ற விபரங்களுக்கும் **ஆராய்ச்சியாளர் மருத்துவர்: மா சுமதி** (பட்டமேற்ப் படிப்பாளர், குழந்தை மருத்துவத் துறை) அவர்களை எந்த நேரத்திலும் தொடர்பு கொள்ளலாம். கைப்பேசி எண்: 9176973238. மேலும் இந்த ஆராய்ச்சிக்கு தக்க அனுமதிச் சான்று (IEC) பெறப்பட்டுள்ளது.

இந்த மருந்து முற்றிலும் பாதுகாப்பான மூலிகை பொருட்களைக் கொண்டு தயாரிக்கப்பட்டுள்ளது. பக்க விளைவுகளை ஏற்படுத்தாது. மேலும் உணவு முறையில் மருத்துவரால் கூறப்படும் பத்தியம் காக்குமாறு அறிவுறுத்தபடுகிறது.

இது சம்பதமான தங்களது அனைத்து விவரங்களும் ரகசியமாக வைக்கப்படும் என உறுதி அளிக்கிறேன்.

இதில் பயணப்படி முதலிய எந்த உதவித் தொகையும் வழங்கப்படமாட்டாது.

இந்த ஆராய்ச்சியின் போது உடலுக்கு வேறு பாதிப்பு ஏற்படும் பட்சத்தில் அறிஞர் அண்ணா மருத்துவமனையில் தக்க சிகிச்சை அளிக்கப்படும்.

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CHENNAI – 600 106

POST- GRADUATE DEPARTMENT OF KUZHANTHAI MARUTHUVAM

CLINICAL STUDY ON **"OMA LEGIUM & MUSUTTAI ENNAI"** IN THE TREATMENT OF **"SIRANGU'' (SCABIES IN CHILDREN)**

FORM X - ADVERSE REACTION REPORTING FORM

SERIAL NO:

OP/IP NO:

NAME: **AGE:** **GENDER:**

DATE OF TRIAL COMMENCEMENT:

DATE OF OCCURRENCE OF THE ADVERSE REACTION: **TIME:**

DESCRIPTION OF ADVERSE REACTION:

MANAGEMENT:

Signature of the Guide **Signature of the Investigator**

Date:

Station:

DEPARTMENT OF KUZHANTHAI MARUTHUVAM

DISSERTATION STUDY ON OMA LEGIUM (INT) &MUSUTTAI ENNAI (EXT) IN SIRANGU (SCABIES)

Investigator: Dr.M.SUMATHI. Place: Arignar Anna Hospital, Chennai-600106.

OP NO/: DATE:

NAME : AGE/SEX:

PARENT NAME:

ADDRESS:

PHONE NO :

COMPLAINS AND DURATION

- NOCTURNAL ITCHING:
- BURROW :
- PUSTULE :
- PAPULOVESICLES :
- PRURITIC PAPULES :
- LESION SEEN IN :

MODE OF ONSET : ACUTE/CHRONIC

ECONOMIC STATE : POOR/MIDDLE/RICH

DIET : VEG/MIXED

PAST HISTORY:

FAMILY HISTORY:

ON EXAMINATION:

CVS :

RS :

HT :

WT :

ENVAGAI THERVU:

NAA: MALAM:

NIRAM: MOOTHIRAM:

MOZHI: NAADI:

VIZHI: SPARISAM:

INVESTIGATIONS:

SAMPLE	BEFORE TREATMENT	AFTER TREATMENT
BLOOD		
TC		
DC		
ESR		
HB		
URINE		
ALB		
SUG		
DEP		
OTHERS		

TREATMENT:

DATE	NOCTURNAL ITCHING	BURROWS	PAPULO VESICLES	PRURITIC PAPULES	PUSTULES	M.O SIGN

GOVT SIDDHA MEDICAL COLLEGE AND HOSPITAL
CHENNAI
Branch -IV KUZHANTHAI MARUTHUVAM
PROFORMA OF CASE SHEET FOR SIRANGU

IP. No	:	Nationality	:
Name	:	Religion	:
Age	:	Date of Admission	:
Sex	:	Date of Discharge	:
Address	:	Diagnosis	:
Informant	:	Medical Officer	:

1. Complaints and duration :
2. History of present illness :
3. History of Past illness :
4. Antenatal history :
5. Birth history :
6. Neonatal history :
7. Developmental history :
8. Nutritional history :
9. Immunization history :
10. Family history :
11. Socio economic status :

General examination

1. Appearance and posture :
2. Nutritional status :
3. Anaemia :
4. Cyanosis :
5. Clubbing :
6. Jaundice :
7. Lymphadenopathy :
8. Abdominal distension :
9. Pedal oedema :

Vital Signs

1. Temperature :
2. Pulse rate :
3. Respiratory rate :
4. Heart rate :
5. Blood pressure :

Anthropometry

a. Height :

b. Weight :

c .Chest circumference :

SIDDHA ASPECTS

Nilam

1. Kurinji :
2. Mullai :
3. Marutham :
4. Neithal :
5. Paalai :

Paruvakalam

1. Kaar :
2. Koothir :
3. Munpani :
4. Pinpani :
5. Elavenil :
6. Muthuvenil :

Poripulangal

1. Mei
2. Vai :
3. Kan :
4. Mooku :
5. Sevi :

Kanmenthiriyam

1. Kai :
2. Kaal :
3. Vaai :
4. Eruvai :
5. Karuvai :

Uyir thathukkal

Vadham

1. Praanan :
2. Abaanan :
3. Viyaanan :
4. Uthaanan :
5. Samaanan :
6. Naagan :
7. Koorman :
8. Kirukaran :
9. Devathathan :
10. Dhananjeyan :

Pitham

1. Analpitham :
2. Ranjagam :
3. Saadhagam :
4. Praasagam :
5. Aalosagam :

Kabam

1. Avalambagam :
2. Kiletham :
3. Pothagam :
4. Tharpagam :
5. Santhigam :

Udal Kattugal

1. Saaram :
2. Senneer :
3. Oon :
4. Kozhuppu :
5. Enbu :
6. Moolai :
7. Sukkilam / Suronitham:

Envagai Thervugal

1. Naadi :
2. Sparisam :
3. Naa :
4. Niram :
5. Mozhi :
6. Vizhi :
7. Malam :
8. Moothiram :

MODERN ASPECTS

1. Respiratory System :
2. Cardiovascular system :
3. Gastro intestinal system :
4. Central nervous system :
5. Excretory system :

Laboratory investigations

Blood

TC :

DC :

ESR :

½ hr :

1 hr :

Hb% :

Urine

Albumin :

Sugar :

Deposits :

Stools

Ova :

Cyst :

Other Investigations

Investigation - Siddha aspect

1. Neer kuri

Niram :

Edai :

Manam :

Nurai :

Enjal :

2. **Neikuri**

3. Daily progress

Date	Symptoms	Medicine

அரசினர் சித்த மருத்துவக் கல்லூரி

அறிஞர் அண்ணா இந்திய மருத்துவமணை சென்னை-106

சிரங்கு நோயாளிகள் கடைப்பிடிக்க வேண்டிய உணவு வழிமுறைகள்

உணவில் சேர்க்க வேண்டியவை :

- பச்சைகாய்கறிகள்
- கீரைவகைகள்
- திரிதோடசமபொருட்கள் (ஏலம், மஞ்சள், சீரகம், பெருங்காயம், மிளகு, சுக்கு, வெந்தயம், பூண்டு)
- முளைகட்டியதானியங்கள்
- பழவகைகள்
- தண்ணீர்

உணவில் தவிர்க்க வேண்டியவை

- வரகு, கம்பு, சோளம், வாழைக்காய், பாகற்காய்
- மீன்வகைகள், முட்டை, கருவாடு, கோழிக்கறி
- கத்தரிக்காய்
- புளி
- ஊறுகாய்வகைகள்

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Contact: 9710437419, Admin: 044 - 42691289

Issued to : **Dr. M.SUMATHI**
Purpose : Physicochemical Analysis
Project ID : NRS/AS/0019/01/2017
Formulation : Oma Legium
Protocol : As per PLIM Guideline

Date: 29/3/2017

Final Test report

- **Physicochemical Evaluation Report of Oma Legium**

S.No	Parameter	Mean (n=3) SD
1.	*Loss on Drying at 105 °C (%)*	39.43 ± 1.98
2.	*Total Ash (%)*	5.66 ± 1.69
3.	*Total Reducing sugar (%w/v)*	22.76 ± 1.09
4.	*Total fat content (%w/v)*	6.75 ± 1.14
5.	*pH*	6

- **Heavy Metal Analysis Report of Oma Legium**

Element	Concentration (mg/L)	Upper Limit (mg/L)
Cadmium (Cd)	BDL	0.299

BDL- Below Detective Level

- **Sterility Test report of Oma Legium**

Test	Specification	Result	Method
E-coli	Absent	Absent	As per AYUSH specification
Salmonella	Absent	Absent	
Staphylococcus Aureus	Absent	Absent	
Pseudomonas Aeruginosa	Absent	Absent	

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CERTIFICATE

This is to certify that the project entitled "**ACUTE AND SUB-ACUTE TOXICITY EVALUATION OF OMA LEGIUM IN RATS**" has been approved by the Institutional Animal Ethics Committee of Sathyabama University, Chennai.

IAEC Approval No.: **SU/CLATR/IAEC/VII/041/2016**
Principal Investigator: Dr. M. Sumathi
Animal Sanctioned: *Rattus norvegicus* /Wistar Albino rats
Female: 15; Male: 9; Total: 24 (Twenty Four)
Date: 05.10.2016

DR. R. SELVARAJ
Member Secretary

DR.R.ILAVARASAN
CPCSEA Nominee

LABORATORY ANIMAL TECHNOLOGY AND RESEARCH (CLATR) * CENTRE FOR
SATHYABAMA UNIVERSITY
Chennai - 600 119

The Tamil Nadu Dr.M.G.R.Medical University

69,Anna Salai,Guindy,Chennai - 600 032.

This Certificate is awarded to Dr/Mr/Mrs.....M:. Sumathi.....

for participating as ~~Resouree~~ ~~Person~~ / Delegate in the Eighteenth Workshop on

" RESEARCH METHODOLOGY & BIOSTATISTICS "

FOR AYUSH POST GRADUATES & RESEARCHERS

Organized by the Department of Siddha

The Tamil Nadu Dr. M.G.R. Medical University from 20 th to 24 th July 2015.

Dr.N.KABILAN, M.D.(Siddha)
READER,DEPT.OF SIDDHA

Prof. **Dr.P.ARUMUGAM,** M.D.,
REGISTRAR i/c

Prof. **Dr.D.SHANTHARAM,** M.D., D.Diab.,
VICE - CHANCELLOR

सिद्ध केंद्रीय अनुसन्धान संस्थान

(सी.सी.आर.एस., चेन्नई, आयुष मंत्रालय, भारत सरकार)

अण्णा सरकारी अस्पताल परिसर, अरुम्बाक्कम, चेन्नई - 600106

SIDDHA CENTRAL RESEARCH INSTITUTE

(Central Council for Research in Siddha, Chennai,
Ministry of AYUSH, Government of India)
Anna Govt. Hospital Campus, Arumbakkam, Chennai - 600106
E-mail: crisiddha@gmail.com Phone: 044-26214925, 26214809

24th May 2016

CERTIFICATE

Certified that the plant/drugs submitted for identification by Dr. M. Sumathi, PG 2nd year, Department of Kuzhanthai maruthuvam, Government Siddha Medical College, Arumbakkam, Chennai - 600 106, are identified as

1. Parangipattai	-	*Smilax china* L. (Tuberous root)
2. Karpogarisi	-	*Cullen corylifolium* (L.) Medik. (Fruit) Syn. *Psoralea corylifolia* L.
3. Omam	-	*Trachyspermum ammi* (L.) Sprague (Fruit) Syn. *Carum copticum* (L.) Link.
4. Kukil	-	*Shorea robusta* Gaertn. (Resin)
5. Amukkurak-kizhangu	-	*Withania somnifera* (L.) Dunal (Root)
6. Musuttai	-	*Rivea hypocrateriformis* Choisy (Leaf) Syn. *R. ornata* Aitch.

Sasikala Ethirajulu

Sasikala Ethirajulu
Consultant (Pharmacognosy)

P.Sathiyarajeswaran
Assistant Director Incharge

GOVERNMENT SIDDHA MEDICAL COLLEGE

Arumbakkam, Chennai-106

Communication Of The Decision Of Institutional Ethics Committee (IEC)

IEC No: GSMC-CH-ME-4/021/2015

Protocol title:

AN OPEN CLINICAL STUDY ON SIRANGU(SCABIES) IN CHILDERN

WITH THE EVALUATION SIDDHA TRAIL DRUG OMA LEGIUM(INTERNAL)

WITH (EXTERNAL) MUSUTTAI ENNAI

Principal Investigator: DR. M.Sumathi.

Name & Address of Institution:

Government Siddha Medical College,

Arumbakkam, Chennai-106

☑ New Review ☐ Revised Review ☐ Expedited Review

Date of review (DD/MM/YY): 26.03.2015

Date of Previous Review, If Revised Application:

Decision of the IEC

☑ Recommended ☐ Recommended with suggestions

☐ Revision ☐ Rejected

Suggestions / Reasons / Remarks:

1. Add external drug Musuttai ennai as another arm.
2. Sample size 40 patient, comparitive study trail - 20 internal medicine only, 20 patients internal & external medicine.

Recommended for a period of 1 year
from date of completion of preclinical studies :

Please Note:

- Inform IEC immediately in case of any adverse events/serious drug reaction.
- Seek IECapproval in case of any change in the study procedure, site and investigator
- This approval is valid only for period mentioned above
- IEC member have the right to review the trial with prior intimation.

Dr.P.Jeyaprakashnarayanan
Chairman

Dr. V.Banumathi
Member Secretary

INSTITUTIONAL ETHICS COMMITTEE

Date:

Sub: IEC review of research proposals.

Ref: Your letter dated

MEMBERS	PARTICIPATION	SIGNATURE
DR.P.JEYAPRAKASH NARAYANAN M.D(S)., Chairman		
DR.V.BANUMATHI M.D(S)., Member Secretary		
DR.N.KABILAN M.D(S)., Clinician- Siddha	✓	26/3/15
DR.P.SATHIYA RAJESWARAN M.D(S)., Clinician- Siddha	✓	26/3/15
DR.G.AADINAAATH REDDY,M.Pharm, Ph.D., Pharmacologist	✓	26/03/15
DR.S.THILAGAVATHY Msc.,Ph.D., Social Scientist	✓	26/3/15
DR.T.MAHALAKSHMI M.A.,Ph.D., Linguistic Expert	✓	
DR.P.VIDYA M.B.B.S., DMRD., Modern Medicine Expert	✓	26/3/15
MR.P.SARAVANAN., Puplic Person	✓	

26/3/15.

Dr.P.Jeyaprakashnarayanan
Chairman

Dr.V.Banumathi
Member Secretary

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E-mail: nobleresearchsolutions@gmail.com
Contact: 9710437419, Admin: 044 - 42691289

Issued to : Dr. M.SUMATHI

Date: 29/3/2017

- Preliminary Phytochemical Evaluation Report of Oma Legium

PHYTOCOMPONENTS	OL
ALKALOIDS	+
FLAVONOIDS	+
GLYCOSIDES	+
STEROIDS	-
CARBOHYDRATES	+
TRITEREPNOIDS	+
COUMARINS	+
PHENOLS	+
CARDIAC GLYCOSIDES	-
TANNINS	+
SAPONINS	+
PROTEINS	+
ANTHOCYANIN	-
BETACYANIN	+
QUINONES	-

+ Indicates positive

- Indicates Negative

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E-mail: nobleresearchsolutions@gmail.com
Contact: 9710437419, Admin: 044 - 42691289

Date: 29.03.2017

To,

Dr. M.Sumathi
Govt Siddha Medical College,
Arumbakkam, Chennai, Tamil Nadu 600106

Project Id : **NRS/AS/0019/01/2017**

This is to certify that Dr. M.Sumathi from Govt Siddha Medical College, Arumbakkam, Chennai has carried out the following activity at our facility for the trial drug *Oma Legium (OL)*

S.No	Study Description	Annexure no
1.	Standardization and Physicochemical Evaluation of study drug *Oma Legium (OL)*	I
2.	Anti-Microbial Profiling of trial drug *Oma Legium (OL)*	II
3.	Docking study against selective target receptor	III

Note:

- *Annexures was attached as a separate enclosure along with this report.*

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Anti- Microbial Profiling of Oma Legium

Issued to : Dr. M.SUMATHI
Project ID : NRS/AS/0019/01/2017
Formulation : Oma Legium

Date: 29/3/2017

Organisms used for Anti-Bacterial Activity

s.no	organisms	Type
1.	*Staphylococcus aureus*	*Gram-positive*
2.	*Streptococcus pyogenes*	*Gram-positive*

Organisms used for Anti-Fungal Activity

s.no	organisms
1.	*Candida albicans*
2.	*Aspergillus niger*

Zone of Inhibition data of Anti-Microbial activity in mm

Sample Code	Streptococcus pyogenes			Staphylococcus aureus			Candida albicans			Aspergillus niger		
Concentration	100 µg	200 µg	300 µg	100 µg	200 µg	300 µg	100 µg	200 µg	300 µg	100 µg	200 µg	300 µg
OL	2	4	9	-	-	-	-	-	-	-	-	-
Ciprofloxacin (5µg)	25			26			NA			NA		
Fluconazole (25µg)	NA			NA			19			16		

- = Not active NA = Not Applicable

Conclusion

From the results of the present study it was concluded that the sample OL was effective against ***Streptococcus pyogenes*** *and not active against* ***Staphylococcus aureus Candida albican and Aspergillus niger***

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Molecular Docking Study Report

Issued to : Dr. Sumathi
Purpose : Computational Analysis
Project ID : NRS/AS/0019/01/2017
Formulation : Oma Legium
Indication : Scabies/ Immuno Modulatory/ Anti Allergic
Soft Ware : Auto Dock 4

Date: 29/3/2017

Compounds / Drug Selected for Docking based on literature

- Beta pinene
- Carvacrol
- Thymol

Receptors / Target protein and Standard Drug Selected for Docking

Name of the Protein	PDB code	Standard antagonist
Histamine 1 receptor	3RZE	Cetirizine
Prostaglandin H2 synthases	1igx	Salycilic acid
Cyclooxygenase I	3KK6	Ibuprofen
Cyclooxygenase 2	6COX	Celecoxib

1. **Docking against Cyclooxygenase I**
   Out of three compound's Betapinene has 6 interactions (60%) similar to that of the standard Ibuprofen hence it has promising COX 1 inhibition activity similarly other compound Carvacrol has 40% percentage similar interaction to that of the standard hence both compounds has COX 1 inhibition activity. Compound Thymol has no COX1 inhibition activity.

2. **Docking against Cyclooxygenase II**
   Out of three compound's Betapinene and Carvacrol has 3 interactions (60%) similar to that of the standard Celecoxib hence it has promising COX 2 inhibition activity similarly other compound Thymol has 20% percentage similar interaction to that of the standard hence all three compounds has promising COX 2 inhibition activity.

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Molecular Docking Study Report

Issued to : Dr. Sumathi

Date: 29/3/2017

3. **Docking against Prostaglandin H2 synthases**
   Out of three compound's Carvacrol has 8 interactions (53%) similar to that of the standard Citrazine hence it has Histamine 1 Receptor inhibition activity similarly other two compounds thymol has 46% percentage and Betapinene has 26% similar interaction to that of the standard hence all three compounds has promising Histamine 1 receptor inhibition activity.

4. **Docking against Histamine 1 receptor**

Out of three compound's Carvacrol has 4 interactions (90%) similar to that of the standard Citrazine Salicylic acid hence it has Prostaglandin Synthase inhibition activity similarly other two compounds thymol has 40% percentage and Betapinene has 20% similar interaction to that of the standard hence all three compounds has promising Prostaglandin Synthase inhibition activity.

Conclusion

Based on the results of the computational analysis it was concluded that the compound's such as Betapinene, Thymol , Carvacrol present in the formulation Oma Legium possess significant inhibition of COX 1& 2 ,Prostaglandin synthases and Histamine 1blocking activity there it was concluded that this formulation may have promising anti-inflammatory, anti-allergic, immune modulatory activity

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